Medtronic Driver

RAPID EXCHANGE CORONARY STENT SYSTEM

INSTRUCTIONS FOR USE

Medtronic Driver
RAPID EXCHANGE CORONARY STENT SYSTEM

Caution: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

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1. DEVICE DESCRIPTION

The Medtronic Driver Rapid Exchange Coronary Stent System consists of a balloon-expandable intracoronary stent premounted on an extended pressure balloon delivery system. The balloon delivery system has two radiopaque markers to aid in the placement of the stent during fluoroscopy. At the transition between the distal and proximal portions of the catheter shaft there is a guidewire entry/exit port that provides the rapid exchange feature of this device. The delivery system is compatible with 0.014" guidewires and has a useable length of 135 cm.
The Driver Coronary Stent is manufactured from a cobalt alloy. The coronary stents are formed from laser fused elements. The stents are provided in multiple lengths and diameters.

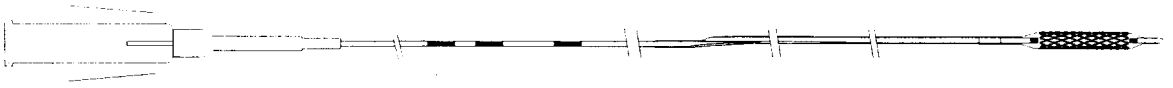

Figure 1. Medtronic Driver Rapid Exchange Delivery System

Package contains one coronary stent premounted on a custom stent delivery system. Sterile, non-pyrogenic in unopened, undamaged packages. Intended for single use only. Do not resterilize. Sterilized by e-beam radiation. Store in a cool, dry, dark place. Use by the "Use By" date noted on the package.

CAUTION: Should there be damage to the package, do not use.

Table 1. Driver Coronary Stent Delivery System Specifications

Stent Diameter	Stent Lengths Available	Minimum Guiding Catheter Compatibility*	Stent Deployment Pressure	Rated Burst Pressure (RBP)	% Stent Free Area
3.0 mm	9,12,15,18,24, 30 mm	0.056 inch	9 atm	16 atm	81
3.5 mm	9,12,15,18,24, 30 mm	0.056 inch	9 atm	16 atm	83
4.0 mm	9,12,15,18,24, 30 mm	0.056 inch	9 atm	16 atm	85

* See manufacturer's specifications for (Fr.) equivalent.

2. INDICATIONS FOR USE

The Medtronic Driver Rapid Exchange Coronary Stent System is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete *de novo* or restenotic lesions with reference vessel diameters of 3.0 – 4.0 mm and ≤ 30 mm in length using direct stenting or pre-dilatation. Outcome beyond 270 days for this permanent implant is unknown at present.

3. CONTRAINDICATIONS

The Medtronic Driver Rapid Exchange Coronary Stent System is contraindicated for use in:

- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.
- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon.

4. WARNINGS AND PRECAUTIONS

(See also Individualization of Treatment.)

- Judicious selection of patients is necessary since the use of this device carries the associated risk of subacute thrombosis, vascular complications and/or bleeding events. Administration of appropriate anticoagulant, antiplatelet and coronary vasodilator therapy is critical to successful stent implantation and follow-up.

- Patients allergic to cobalt, chromium or nickel may suffer an allergic reaction to this implant.

- Only physicians who have received appropriate training should perform implantation of the stent.

- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.

- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized coronary stents is unknown at present.

- When multiple stents are required stent materials should be of similar composition. Placing multiple stents of different materials in contact with each other may increase the potential for corrosion. Data obtained from *in vitro* corrosion tests using a F562 CoCr alloy stent (Medtronic Driver Coronary Stent) in combination with a 316L stainless steel alloy stent (Medtronic S7 Coronary Stent) does not suggest an increased risk of *in vivo* corrosion

- If the physician encounters difficulty while trying to cross the lesion by direct stenting and determines the lesion to be uncrossable, this patient should be treated per predilatation practice. The stent (the same stent if undamaged) or a new stent of the same kind, should then be advanced and deployed with pre-dilatation.

4.1 Stent Handling – Precautions

- **For single use only**. Do not resterilize or reuse. Note product "Use By" date.
- **Do not remove stent from the Stent Delivery System** as removal may damage the stent and/or lead to stent embolization. The Medtronic Driver Rapid Exchange Coronary Stent System is intended to perform as a system. The Medtronic Driver Stent is not designed to be crimped onto another delivery device.
- Stent Delivery System should not be used in conjunction with any other stents.
- Special care must be taken not to handle or in any way disrupt the stent position on the delivery device. This is most important during catheter removal from packaging, placement over guidewire, and advancement through rotating hemostatic valve adapter and guiding catheter hub.
- Excessive manipulation, e.g., rolling the mounted stent, may cause dislodgement of the stent from the delivery balloon.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as it may cause uneven expansion and difficulty in deployment of the stent.

4.2 Stent Placement – Precautions

- **Do not prepare or pre-inflate the Stent Delivery System prior to stent deployment**, other than as directed. Use balloon purging technique described in section 9.3 Delivery System Preparation.
- Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stented portion, and may cause acute closure of the vessel requiring additional intervention (e.g., CABG, further dilatation, placement of additional stents, or other).
- When treating multiple lesions, the distal lesion should be initially stented, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent when placing the distal stent and reduces the chances for dislodging the proximal stent.
- Do not expand the stent if it is not properly positioned in the vessel (see section 9.7-Stent/System Removal – Precautions).
- Placement of the stent has the potential to compromise side branch patency.
- **Do not exceed Rated Burst Pressure as indicated on product label.** Balloon pressures should be monitored during inflation (see Compliance Chart - Table 4). Use of pressures higher than those specified on product label may result in a ruptured balloon and potential intimal damage and dissection.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the coronary vasculature and/or the vascular access site. Complications can include bleeding, hematoma or pseudoaneurysm.

4.3 Post-Implant– Precautions

- Care must be exercised when **crossing a newly deployed stent** with an intravascular ultrasound (IVUS) catheter, a coronary guidewire, or a balloon catheter to avoid disrupting the stent geometry.

4.4 MRI Statement

The Driver Coronary Stent has been shown to be MRI safe immediately following implantation at a field strength of up to 1.5 Tesla, a maximum spatial gradient of 5.25 Tesla/meter (or 525 gauss/cm), gradient magnetic fields of 6.3 mT/m or less and a maximum whole body averaged specific absorption rate (SAR) of 4 W/kg for 15 minutes of MR imaging. MR imaging may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

5. OBSERVED ADVERSE EVENTS

The Medtronic (Driver) DeNovo and Restenotic Registry enrolled 298 patients in a non-randomized, multi-center study. These patients form the basis of the observed events reported in the following section.

5.1 Driver DeNovo and Restenotic Registry

A total of 298 patients were enrolled in a multi-center registry to evaluate the safety and efficacy of the Medtronic Driver Coronary Stent System for treatment of symptomatic coronary artery disease.

The primary endpoint of MACE at 180 days was compared to an objective performance criterion (OPC) of 15% based on a pooled MACE rate derived by pooling the data from the Bard XT Stent EXTRA RCT, Medtronic Micro Stent II SMART RCT, and Medtronic BeStent I (BEST) & BeStent II Registries.

Adverse events reported during the first six and nine months are shown in Table 2. A total of 25 of 298 patients (8.4%) who received the Medtronic Driver stent experienced one or more adverse events during the nine months of follow-up.

A total of 4 of the 298 (1.3%) patients who received the Driver stent died during the clinical study. These out-of-hospital deaths were all non-cardiac related: one secondary to ovarian cancer at 43 days post-procedure,one secondary to a brain tumor at 136 days post-procedure, one due to acute respiratory failure at 242 days post-procedure and one non-specified cancer death at 268 days post-procedure . There were no instances of stent thrombosis during the first 270 days. The incidence of vascular complications was 3.4% (10/298). The rate of bleeding complications was 2.3% (7/298).

There were no (0/298) delivery or device failures reported.

Table 2. Principal Adverse Events Through 180 & 270 Days †. Driver DeNovo and Restenotic Registry

%, (Number) [95% confidence interval)

Complication*	Medtronic Driver Stent (N=298) 180-Day Results	Medtronic Driver Stent (N=298) 270-Day Results
Adverse Event§	**7.7%** (23)[5.0%,11.4%]	**8.4%** (25)[5.5%,12.1%]
In-Hospital	**5.7%** (17)[3.4%,9.0%]	**5.7%** (17)[3.4%,9.0%]
Out-of-Hospital	**2.0%** (6)[0.7%,4.3%]	**2.7%** (8){1.2%,5.2%]
MACE	**5.7%** (17)[3.4%,9.0%]	**10.1%** (30) [6.9%,14.1%]
In-Hospital	**1.7%** (5)[0.5%,3.9%]	**1.7%** (5)[0.5%,3.9%]
Out-of-Hospital	**4.0%** (12)[2.1%,6.9%]	**8.4%** (25) [5.5%,12.1%]
Death	**0.7%** (2)[0.1%,2.4%]	**1.3%** (4) [0.4%, 3.4%]**
In-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Out-of-Hospital	**0.7%** (2)[0.1%,2.4%]	**1.3%** (4) [0.4%,3.4%]**
Q-wave MI	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
In-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Out-of-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Non Q-wave MI	**1.7%** (5)[0.5%,3.9%]	**1.7%** (5)[0.5%,3.9%]
In-Hospital	**1.7%** (5)[0.5%,3.9%]	**1.7%** (5)[0.5%,3.9%]
Out-of-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Target Lesion Revascularization	**3.4%** (10) [1.6%,6.1%]	**7.0%** (21) [4.4%, 10.6%}
In Hospital -PTCA	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
In Hospital-CABG	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Out-of-Hospital PTCA	**2.7%** (8)[1.2%,5.2%]	**6.4%** (19) [3.9%, 9.8%]
Out-of-Hospital CABG	**0.7%** (2) [0.1%,2.4%]	**0.7%** (2) [0.1%,2.4%]
Emergent CABG	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
In-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Out-of-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Stent Thrombosis	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
In-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Out-of-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Bleeding (procedural transfusion)	**2.3%** (7)[0.9%,4.8%]	**2.3%** (7)[0.9%,4.8%]
In-Hospital	**2.0%** (6)[0.7%,4.3%]	**2.0%** (6)[0.7%,4.3%]
Out-of-Hospital	**0.3%** (1)[0.0%,1.9%]	**0.3%** (1)[0.0%,1.9%]
CVA	**0.3%** (1)[0.0%,1.9%]	**0.3%** (1)[0.0%,1.9%]
In-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Out-of-Hospital	**0.3%** (1)[0.0%,1.9%]	**0.3%** (1)[0.0%,1.9%]
Vascular Complications	**3.4%** (10)[1.6%,6.1%]	**3.4%** (10)[1.6%,6.1%]
In-Hospital	**2.7%** (8)[1.2%,5.2%]	**2.7%** (8)[1.2%,5.2%]
Out-of-Hospital	**0.7%** (2)[0.1%,2.4%]	**0.7%** (2)[0.1%,2.4%]
Stent Delivery Failures	**0.0%** (0) [0.0%, 1.2%]	**0.0%** (0) [0.0%, 1.2%]

*Complications are based on patient totals. Seven patients had multiple adverse events: one patient had 3 vascular complications, four patients had 2 vascular complications), one patient had 1 non-Q MI and 1 bleeding. complication), and one patient had1 non-Q MI and 1 vascular complication.

§Adverse Event= Death, Q or Non-Q wave MI, Emergent CABG, Stent Thrombosis, CVA, Bleeding Complications, and Vascular Complications.

**All four deaths were non-cardiac.

Definitions for the terms used in Table 2 are found in the footnotes to Table 3.

5.2 Potential Adverse Events

Potential adverse events that may be associated with the use of a coronary stent in native coronary arteries (including those listed in Table 2) are listed below in order of severity:

- Death
- Emergency Coronary Artery Bypass Graft Surgery (CABG)
- Stroke/Cerebrovascular Accidents
- Cardiac tamponade
- Stent thrombosis or occlusion
- Total occlusion of coronary artery
- Acute myocardial infarction
- Restenosis of stented segments
- Perforation
- Arrhythmias, including ventricular fibrillation & ventricular tachycardia
- Dissection
- Emboli, distal (air, tissue or thrombotic emboli)
- Stent embolization
- Hemorrhage requiring transfusion
- Pseudoaneurysm, femoral
- Spasm
- Myocardial ischemia
- Hypotension/Hypertension
- Allergic reaction to drugs/contrast medium/stent material
- Peripheral ischemia
- Peripheral nerve injury
- Infection and pain at the insertion site
- Hematoma

6. CLINICAL TRIAL RESULTS

6.1 Driver DeNovo and Restenotic Registry

6.1.1 Purpose

The purpose of the Driver Registry was to evaluate the safety and efficacy of the Medtronic Driver stent for the treatment of single *de novo* or restenotic post-PTCA (non-stented) lesions in native coronary arteries.

6.1.2 Conclusions

The Driver Registry demonstrated the 180-day and 270-day safety and efficacy of the Driver stent for treatment of patients with *de novo* or restenotic lesions in native coronary arteries.

6.1.3 Design

A prospective, multi-center non-randomized study was conducted at 23 North American clinical sites enrolling 298 patients. Patients were 18 years of age or older with clinical evidence of ischemic heart disease or a positive functional study undergoing elective treatment for a single *de novo* or restenotic (post PTCA, non-stented) lesion in a native coronary artery. Eligible patients had visually estimated stenosis $\geq$ 50% and < 100% in a lesion $\leq$ 30 mm in length located in a major coronary artery or major side branch $\geq$ 3.0 mm and $\leq$ 4.0 mm in diameter.

The primary endpoint in the Driver DeNovo and Restenotic Registry was Major Adverse Cardiac Event (MACE) rate defined as the composite of death, Q wave and non-Q wave myocardial infarction, emergent bypass surgery, or target lesion revascularization (TLR) at 180 days. The primary endpoint was analyzed on an intent-to-treat basis, defined as patients who had the study device introduced into the guide catheter after determination that the subject and the target lesion met all inclusion criteria and none of the exclusion criteria.

The primary endpoint of MACE at 180 days was compared to an objective performance criterion (OPC) of 15% plus delta of 6%, based on a pooled MACE rate derived from the Bard XT Stent EXTRA RCT, Medtronic Micro Stent II SMART RCT, and Medtronic BeStent I (BEST) & BeStent II Registries. These studies had a range of 12.1% to 15.7% for MACE at 6 months compared to the Driver Registry 6 month MACE rate of 5.7% (17/298).

Secondary endpoints, (including acute success, target vessel failure (TVF) in hospital, at 14, 30, 180 and 270 days, clinically driven target lesion revascularization (TLR) at 180 and 270 days, binary angiographic restenosis ($\geq$ 50% in-stent diameter stenosis) at 180 days in the 101 patient subset, late loss at 180 days and ischemic, bleeding and vascular complications) were analyzed on a per-protocol evaluable basis, defined as patients who had successful procedures and were available for follow-up.

All patients received the hospital's standard anti-coagulation/anti-platelet regimen for coronary stent implantation. The ACT was kept at therapeutic levels for Percutaneous Coronary Intervention per the hospital standard.

6.1.4 Demographics

Of the 298 patients enrolled, baseline demographics and clinical characteristics showed a mean age of 62.6 years (range 26 to 88 years), 68.1% (203/298) were men, 27.6% (82/297) had a history of diabetes mellitus, 75.9% (221/291) had hyperlipidemia requiring treatment, 28.8% (83/288) were current smokers and 68.4% (201/294) had hypertension requiring treatment.

6.1.5 Methods

Patients in the Driver DeNovo and Restenotic Registry underwent balloon angioplasty (1:1 balloon to artery ratio) after which a stent of the appropriate length and diameter was selected and deployed.

The Medtronic Driver Coronary Stent System could be repressurized up to 16 atm to further dilate the stent to assure complete apposition of the stent to the artery wall. If needed, further inflations were performed with a non-compliant balloon with a balloon-to-artery ratio of 1:1.
The anticoagulation regimen administered to 100% of the patients included 325 mg/day of aspirin for at least 14 days; plus either ticlopidine, 250 mg b.i.d. or clopidogrel 75 mg q.d for 14 days. Glycoprotein IIbIIIa platelet inhibitors were administered to 32.6% (97/298) of the patients during the index procedure.

Clinical or telephone follow-up was conducted in-hospital, and at 14, 30, 180 and 270 days post-procedure. A subset of 27.8% (83/298) patients underwent follow-up angiography at the 180 day clinical follow-up. Data monitoring was conducted by Medtronic personnel. Angiographic films were analyzed and revascularizations were adjudicated by an independent Angiographic Core Laboratory. An independent Clinical Events Committee adjudicated all other primary endpoints and Major Adverse Cardiac Events.

6.1.6 Results

The Driver Registry 180 day TVF rate was 5.0% (15/298) and the TVF rate at 270 days was 9.7% (29/298). Adverse events for both time points are listed in Table 2 and the Principal Safety and Effectiveness results are presented in Table 3.

The primary endpoint of MACE at 180 days was compared to an objective performance criterion (OPC), based on a pooled MACE rate derived from previous AVE/Medtronic/USCI-Bard trials, of 15% plus delta of 6%. Specifically, the OPC of 15% as derived by pooling the data from the Bard XT Stent EXTRA RCT, Medtronic Micro Stent II SMART RCT, and Medtronic BeStent I (BEST) & BeStent II Registries.

A test of the null hypothesis that the observed Driver MACE rate of 5.7% (17/298) is greater or equal to 21% (15% OPC + delta of 6%), provided an Exact Test (one-sided) p-value less than 0.0001, leading to a rejection of this null hypothesis and signifying equivalency with the OPC rate (i.e., Driver MACE rate significantly less than 21%). In a test for superiority, the Driver MACE rate was significantly less than the OPC of 15% itself (p=0.0082).

Table 3. Principal Effectiveness and Safety Results - Medtronic Driver Stent

Efficacy Measures	**Medtronic Driver Stent (N=298)**
Post-Procedure In-Stent Minimal Lumen Diameter (mm) Mean±SD (N) Range (min,max)	 2.90±0.42 (284) (1.52,4.12)[2.85 , 2.94]
Procedure In-Stent Percent Diameter Stenosis (% DS) Mean±SD (N) Range (min,max)	 3.05±10.50 (284) (-32.31,41.12)[1.83 , 4.27]
Device Success	**100.0%** (298)[98.8%, 100%]
Procedure Success	**98.3%** (293)[96.1%, 99.5%]
Binary Restenosis Rate	**15.7%** (13/83)
TLR-free at 180 Days*	**96.2%** [94.7%, 97.7%]
TLR-free at 270 Days*	**91.2%** [86.5%, 95.8%]
TVR-free at 180 Days*	**95.5%** [93.5%, 96.9%]
TVR-free at 270 Days*	**90.0%** [85.1%, 95.0%]
TVF-free at 180 Days*	**92.8%** [90.8%, 94.8%]
TVF-free at 270 Days*	**88.3%** [83.1%, 93.6%]
Safety Measures & Other Clinical Events	**Medtronic Driver Stent (N=298)**
In-Hospital MACE (Death, QMI,NQMI, TLR, Emergent CABG)	**1.7%** (5)[0.5%, 3.9%]
Out-of-Hospital MACE (Death, QMI, NQMI, TLR, Emergent CABG)	**8.4%** (25) [5.5%,12.1%]
MACE to 180 days (Death, QMI, NQMI, TLR, Emergent CABG)	**5.7%** (17)[3.4%, 9.0%]
MACE to 270 days (Death, QMI, NQMI, TLR, Emergent CABG)	**10.1%** (30) [6.9%,14.1%]
TLR rate at 180 days	**3.4%** (10) [1.6%,6.1%]
TLR rate at 270 days	**7.0%** (21) [4.4%, 10.6%}
TVR rate at 180 days	**1.7%** (5)[0.5%,3.9%]
TVR rate at 270 days	**2.3%** (7)[0.9%, 4.8%]
TVF rate at 180 days	**6.7%** (20) [4.1%, 10.2%]
TVF rate at 270 days	**9.7%** (29) [6.6%, 13.7%]
Bleeding Complications	**2.3%** (7)[0.9%,4.8%]
CVA	**0.3%** (1)[0.0%,1.9%]
Vascular Complications	**3.4%** (10)[1.6%,6.1%]
Stent Thrombosis	**0.0%** (0)[0.0%,1.2%]

MACE: Major Adverse Cardiac Event (includes death, MI, and emergent CABG or target lesion revascularization).

TLR free: No target lesion revascularization.
TVR free: No target vessel revascularization.
TVF free: No death, any MI or target vessel revascularization.
Binary restenosis: 50% or greater in-stent diameter stenosis at the follow-up angiogram.
Stent Thrombosis: Stent thrombosis was defined as total thrombotic stent occlusion documented by angiography.
In-hospital major clinical event: death, MI, emergent CABG, repeat target lesion revascularization, stent thrombosis, or stroke prior to discharge, as determined by the independent Clinical Events Committee.
Out-of-hospital major clinical event: death, MI, emergent CABG, repeat target lesion revascularization, stent thrombosis, or stroke after discharge, as determined by the independent Clinical Events Committee.
Vascular complications; may include pseudoaneurysm, arteriovenous fistula, peripheral ischemia/nerve injury or vascular event requiring transfusion or surgical repair.
Bleeding complications: transfusions due to blood loss resulting from the percutaneous revascularization procedure.
CVA: sudden onset of vertigo, numbness, dysphasia, weakenss, visual field defects, dysarthria or other focal neurological deficits due to vascular lesions of the brain, such as hemorrhage, embolism, thrombosis, or rupturing aneurysm, that persists greater than 24 hours.
Device success: Attainment of <30% in-stent residual stenosis using the randomized treatment strategy only.
Procedure success: <50% stenosis in-stent (or in-lesion if no in-stent measurement available) and freedom from in-hospital major adverse cardiac events (death, MI, emergent CABG, or repeat target lesion revascularization).
*Survival estimates by Kaplan-Meier method; Standard Error estimates by Greenwood formula

6.2 PREDICT Trial

Based on acceptable performance in *de novo* lesions and the similarities in design and manufacture of the DRIVER Coronary Stent System to the Medtronic S670™ and Medtronic S7 Coronary Stent Systems, the following study, which evaluated direct stenting using the Medtronic S670 Coronary Stent, also supports the suitability of direct stenting for delivery of the Medtronic Driver Coronary Stent System.

The PREDICT Trial was a prospective, multi-center study using the S670™ OTW Coronary System randomized to either direct stenting or standard predilatation deployment technique. The study was conducted at 37 North American clinical sites and included a total of four hundred (400) randomized patients and sixteen (16) roll-in patients with *de novo* native coronary artery lesions. A clinical events committee adjudicated all major clinical events and clinically driven TLR.

6.2.1 Primary Endpoint

The primary endpoint in the PREDICT Trial was Major Adverse Cardiac Event (MACE) rate defined as the composite of death, Q wave and non-Q wave myocardial infarction, emergent coronary artery bypass surgery, or target lesion revascularization (TLR) at 14 days.

6.2.2 Patients Studied

The 399 patients (65.7% male) treated ranged in age from 29 to 87 years with an average of 64 ± 11.6 (mean ± SD) years. All patients presented with angina or a positive functional study and were undergoing elective single *de novo* lesion treatment in a native coronary artery. Eligible patients had visually estimated stenosis ≤ 15 mm in length in a major coronary artery or major side branch ≥ 3.0 mm and ≤ 4.0 mm in diameter. One patient withdrew consent after randomization but before investigational treatment was attempted.

6.2.3 Methods

Patients in the PREDICT Trial were randomized to either direct stenting (without predilatation) or standard pre-dilatation by balloon angioplasty (1:1 balloon to artery ratio) after which a stent system(s) of the appropriate length and diameter was selected and deployed. The Medtronic AVE S670™ OTW stent delivery system could be repressurized up to 16 atm to further dilate the stent to assure complete apposition of the stent to the artery wall. If needed, further inflations were performed with a non-compliant balloon with a balloon-to-artery ratio of 1:1. Clinical follow-up was conducted up to 6 months.

The anticoagulation regimen administered to 97% (389/399) of the patients at discharge was 325 mg aspirin and either 500 mg ticlopidine or 300 mg clopidogrel. The follow-up regimen administered to 83% (333/399) of the patients was 325 mg/day ASA for at least six month; ticlopidine 250 mg twice a day or clopidogrel 75 mg daily.

Clinical follow-up intervals for all treated PREDICT patients were 14 days, 30 days and 6 months. All patients underwent angiographic follow-up at 6 months for the PREDICT Trial. The study randomization was successful, as both treatment groups were demographically equivalent. All treated randomized patients were included in the intent-to-treat efficacy analysis. The principal effectiveness and safety for the PREDICT Trial for direct stenting versus predilatation are shown in table 4.

6.2.4 Conclusions

The success rate for the direct stenting arm was 92.0% (185/201). The sixteen patients who crossed over to the pre-dilatation arm were treated successfully. There were no statistically significant differences between the two arms with respect to Major Adverse Cardiac Events.

Table 4. Principal Effectiveness and Safety Results PREDICT Trial
S670 PREDICT Patients Treated (N = 399)

Efficacy Measures	Direct Stenting (N=198 Patients, N=201 Lesions)	Pre-Dilatation (N=201 Patients, N=203 Lesions)	All Randomized* (N=399 Patients, N=404 Lesions)	Relative Risk [95% C.I.]	Difference [95% C.I.]	P-value
Primary Device Success	92.0% (185 / 201)	96.6% (196 / 203)	94.3% (381 / 404)	0.95 [0.91,1.00]	-4.5% [-9.0%,0.0%]	0.056
Secondary Device Success	99.5% (200 / 201)	99.0% (200 / 202)	99.3% (400 / 403)	1.00 [0.99,1.02]	0.5% [-1.2%,2.2%]	1.000
Procedure Success	93.9% (186 / 198)	92.5% (185 / 200)	93.2% (371 / 398)	1.02 [0.96,1.07]	1.4% [-3.5%,6.4%]	0.691
Post-Procedure In-Lesion Minimal Lumen Diameter (MLD, in mm)						
Mean±SD (N)	2.54±0.55 (199)	2.56±0.50 (199)	2.55±0.52 (398)	N/A	-0.02 [-0.12,0.09]	0.739
Range (min,max)	(1.34,4.29)	(1.37,4.01)	(1.34,4.29)			
Post-Procedure In-Lesion Percent Diameter Stenosis (% DS)						
Mean±SD (N)	18.9%±9.8% (199)	18.3%±11.1% (199)	18.6%±10.5% (398)	N/A	0.6% [-1.5%,2.6%]	0.585
Range (min,max)	(1.5%,55.6%)	(-27.7%,54.2%)	(-27.7%,55.6%)			
Post-Procedure In-Stent Minimal Lumen Diameter (MLD, in mm)						
Mean±SD (N)	2.92±0.43 (199)	2.98±0.42 (199)	2.95±0.43 (398)	N/A	-0.06 [-0.14,0.03]	0.185
Range (min,max)	(1.84,4.30)	(2.10,4.34)	(1.84,4.34)			
Post-Procedure In-Stent Percent Diameter Stenosis (% DS)						
Mean±SD (N)	5.9%±9.4% (199)	4.5%±9.3% (199)	5.2%±9.4% (398)	N/A	1.4% [-0.5%,3.2%]	0.150
Range (min,max)	(-24.1%,35.8%)	(-34.7%,27.0%)	(-34.7%,35.8%)			
In-Lesion Acute Gain (mm)						
Mean±SD (N)	1.60±0.60 (199)	1.66±0.58 (199)	1.63±0.59 (398)	N/A	-0.06 [-0.18,0.06]	0.302
Range (min,max)	(0.11,3.74)	(0.06,2.97)	(0.06,3.74)			
In-Stent Acute Gain (mm)						
Mean±SD (N)	1.98±0.53 (199)	2.08±0.52 (199)	2.03±0.53 (398)	N/A	-0.10 [-0.20,0.00]	0.056
Range (min,max)	(0.77,3.74)	(0.34,3.59)	(0.34,3.74)			
In-Lesion Binary Restenosis Rate	26.5% (43 / 162)	25.8% (42 / 163)	26.2% (85 / 325)	N/A	0.8% [-8.8%,10.3%]	0.900
In-Stent Binary Restenosis Rate	20.4% (33 / 162)	20.9% (34 / 163)	20.6% (67 / 325)	N/A	-0.5% [-9.3%,8.3%]	1.000
TLR-free to 180 days†	80.2%	82.6%	81.5%	0.97 [0.78,1.21]	-2.4% [-20.0%,15.3%]	0.846
TVR-free to 180 days†	79.3%	79.3%	79.3%	1.00 [0.80,1.26]	0.0% [-18.1%,18.1%]	0.643
TVF-free to 180 days†	72.9%	72.5%	72.7%	1.01 [0.77,1.32]	0.4% [-19.4%,20.1%]	0.677
MACE-free to 180 days†	73.8%	74.5%	74.1%	0.99 [0.76,1.29]	-0.7% [-20.2%,18.9%]	0.770
Safety Measures and Other Clinical Events						
In-Hospital MACE	5.6% (11 / 198)	7.0% (14 / 201)	6.3% (25 / 399)	0.80 [0.37,1.71]	-1.4% [-6.2%,3.3%]	0.681
Out-of-Hospital MACE to 14 days	0.5% (1 / 198)	0.5% (1 / 201)	0.5% (2 / 399)	1.02 [0.06,16.17]	0.0% [-1.4%,1.4%]	1.000
MACE to 14 days	6.1% (12 / 198)	7.5% (15 / 201)	6.8% (27 / 399)	0.81 [0.39,1.69]	-1.4% [-6.3%,3.5%]	0.691
Out-of-Hospital MACE to 180 days	13.1% (26 / 198)	13.9% (28 / 201)	13.5% (54 / 399)	0.94 [0.57,1.55]	-0.8% [-7.5%,5.9%]	0.884
MACE to 180 days	18.7% (37 / 198)	19.4% (39 / 201)	19.0% (76 / 399)	0.96 [0.64,1.44]	-0.7% [-8.4%,7.0%]	0.899
Abrupt Closure to 180 days	0.0% (0 / 198)	1.5% (3 / 201)	0.8% (3 / 399)	0.00 [—,—]	-1.5% [-3.2%,0.2%]	0.248
Subacute Closure to 180 days	0.0% (0 / 198)	0.5% (1 / 201)	0.3% (1 / 399)	0.00 [—,—]	-0.5% [-1.5%,0.5%]	1.000
Stent Thrombosis to 180 days	0.5% (1 / 198)	0.5% (1 / 201)	0.5% (2 / 399)	1.02 [0.06,16.17]	0.0% [-1.4%,1.4%]	1.000
CVA to 180 days	0.0% (0 / 198)	0.0% (0 / 201)	0.0% (0 / 399)	— [—,—]	0.0% [—,—]	N/A
Bleeding Complications to 180 days	1.5% (3 / 198)	1.0% (2 / 201)	1.3% (5 / 399)	1.52 [0.26,8.91]	0.5% [-1.7%,2.7%]	0.684
Vascular Complications to 180 days	7.1% (14 / 198)	4.0% (8 / 201)	5.5% (22 / 399)	1.78 [0.77,4.09]	3.1% [-1.4%,7.6%]	0.194

†. One patient withdrew consent after randomization but before the investigational treatment was attempted and was deregistered.

Primary Device Success = The attainment of a <50% residual in-stent (or in-lesion in the absence of in-stent) stenosis (by QCA) of the target site using the assigned treatment strategy alone, (i.e. only the Medtronic AVE S670™ stent without pre-dilatation if so randomized) during the index catheterization. If QCA was not available, the visual estimate of diameter stenosis was used. Post-dilatation with a high pressure or larger balloon was considered part of the treatment strategy for both arms, but tracked as to frequency. The need for pre-dilatation in patients randomized to direct stenting arm was considered a primary device failure and use of other brands of stents besides the Medtronic AVE S670™.

Secondary Device Success = The attainment of a <50% residual in-stent (or in-lesion in the absence of in-stent) stenosis (by QCA) of the target site using any strategy (including stent withdrawal, pre-dilatation or pre-treatment with another device, and a repeat attempt at stent implantation). If QCA was not available, the visual estimate of diameter stenosis was used. Post-dilatation with a high pressure or larger balloon was considered part of the treatment strategy for both arms, but tracked as to frequency.

Procedure Success = The attainment of a <50% in-stent (or in-lesion in the absence of in-stent) residual stenosis (by QCA) at the target site using any strategy and freedom from Major Adverse Cardiac Events prior to hospital discharge. If QCA was not available, the visual estimate of diameter stenosis was used.

In-Hospital MACE = Death, Q wave or non-Q wave MI, emergent CABG, or target lesion revascularization prior to discharge as determined by the independent Clinical Events Committee.

Out-of-Hospital MACE = Death, Q wave or non-Q wave MI, emergent CABG, or target lesion revascularization from hospital discharge through the 180-day contact, as determined by the independent Clinical Events Committee.

TLR-free = No target lesion revascularization.

TVR-free = No target vessel revascularization.

TVF-free = No death, MI, or target vessel revascularization.

Footnotes are continued on the following page.

MACE-free = No death, MI, emergent CABG, or target lesion revascularization.
Abrupt Closure = Occurrence of new severely reduced flow (TIMI grade 0 or 1) within the target vessel that persisted and required rescue by a non-assigned treatment strategy, or resulted in MI or death.
Subacute Closure = Abrupt closure that occurred after the index procedure was completed and within 30 days of the index procedure.
Stent Thrombosis = Angiographic thrombus or subacute closure within the stented vessel, or any death not attributed to a non-cardiac cause in the absence of documented angiographic stent patency within the first 30 days.
CVA = Acute neurological deficits recorded by the clinical sites that persisted >24 hours.
Bleeding Complications = Defined as transfusions of blood products due to blood loss from the percutaneous revascularization procedure.
Vascular Complications = Defined as hematoma >4 cm, false aneurysm, AV fistula, retroperitoneal bleed, peripheral ischemia/nerve injury, procedure related transfusion or vascular surgical repair.
Acute Gain = Acute gain was defined as the immediate dimensional change in minimal luminal diameter (in mm) that occurred as a result of the procedure, measured by quantitative coronary angiography based on data interpolated from two orthogonal views at baseline and after the final post dilatation.

7. PATIENT SELECTION AND TREATMENT

7.1 Individualization of Treatment

The risks and benefits described above should be carefully considered for each patient before use of the Medtronic Driver Rapid Exchange Coronary Stent System. Patient selection factors to be assessed should include a judgment regarding risk of prolonged anticoagulation. Stenting should be generally avoided in those patients at heightened risk of bleeding (e.g., those patients with recently active gastritis or peptic ulcer disease) (see Contraindications).

Co-morbidities that increase the risk of poor initial results or the risks of emergency referral for bypass surgery (diabetes mellitus, renal failure, and severe obesity) should be reviewed.

Thrombosis following stent implantation is affected by several baseline angiographic and procedural factors. These include vessel diameter less than 3.0 mm, intra-procedural thrombosis, poor distal flow, and/or dissection following stent implantation. In patients that have undergone coronary stenting, the persistence of a thrombus or dissection is considered a marker for subsequent thrombotic occlusion. These patients should be monitored very carefully during the first month after stent implantation.

7.2 Use in Special Populations

The safety and effectiveness of the Medtronic Driver Rapid Exchange Coronary Stent System have not been established in:

- Patients with **unresolved vessel thrombus at the lesion site**.
- Patients with coronary artery **reference vessel diameters < 3.0 mm**.
- Patients with **lesions located in the unprotected left main coronary artery**, **ostial lesions**, or **lesions located at a bifurcation**.
- Patients with diffuse disease or **poor outflow distal** to the identified lesions.
- Patients with recent **acute myocardial infarction** where there is evidence of thrombus or poor flow.
- Patients with **more than two overlapping stents** due to risk of thrombosis or poor flow.
- Patients beyond the **nine month follow-up** period

The safety and effectiveness of using mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters), or laser angioplasty catheters, to treat in-stent stenosis have not been established.

8. CLINICIAN USE INFORMATION

8.1 Inspection Prior to Use

Carefully inspect the sterile package before opening. It is not recommended that the product be used after the "Use By" date. If the integrity of the sterile package has been compromised prior to the product "Use By" date (e.g., damage of the package) contact your local Medtronic, Inc. Representative for return information. If the sterile package appears intact, carefully remove the system from the package and inspect for bends, kinks and other damage. Verify that the stent is located between the radiopaque markers. Do not use if any defects are noted.

8.2 Materials Required

Quantity	Material
	Appropriate guiding catheter. (see Table 1- Device Specifications)
1	20 cc syringe.
	Heparinized normal saline.
1	0.014 inch x 300 cm guidewire.
1	Rotating hemostatic valve.
	Contrast medium diluted 1:1 with heparinized normal saline.
1	Inflation device.
1	Torque device.
Optional	Three-way stopcock.

8.3 Preparation of Delivery System

Step	Action
1	Prepare the guiding catheter and guidewire according to the manufacturer's instructions. The Medtronic Driver Stent Delivery System is compatible with 0.014" guidewires. Refer to product labeling for specific guiding catheter compatibility.
2	Careful stent sizing is important to successful stenting. In general, the stent size should be chosen to match the diameter of the reference vessel and to correspond with the length of the lesion. Slight stent oversizing is preferable to undersizing. **Note:** The inflated balloon diameter measures slightly larger than the labeled stent diameter to allow for stent recoil following expansion.
3	Remove the stent delivery system from the package.
4	Attach the blunt end of a syringe to the distal end of the catheter and flush the Stent Delivery System until fluid exits from the guidewire entry/exit port.
5	Remove protective sheath covering from the stent/balloon. Special care must be taken not to handle the stent or in any way disrupt its placement on the balloon.
6	Inspect the stent to ensure it has not been damaged or displaced from its original position on the balloon. Verify that the stent is positioned between the proximal and distal balloon markers. **Note:** Should there be movement of or damage to the stent, do not use.
7	Flush Stent Delivery System guidewire lumen with heparinized normal saline until fluid exits the distal tip.

8	Fill a 20 cc syringe with 5 cc of contrast/heparinized normal saline mixture (1:1).
9	Attach to delivery system and apply negative pressure for 20-30 seconds.
10	Slowly release pressure to allow negative pressure to draw mixture into balloon lumen.
11	Detach syringe and leave a meniscus of mixture on the hub of the balloon lumen.
12	Prepare inflation device in standard manner and purge to remove all air from syringe and tubing.
13	Attach inflation device to catheter directly ensuring no bubbles remain at connection.
14	Leave on ambient pressure (neutral position). **Note: Do not pull negative pressure on inflation device after balloon preparation and prior to delivering the stent.**
15	Moisten the stent with heparinized normal saline by submerging the stent into a sterile bowl containing the solution. **Note: Do not use gauze sponges to wipe down the stent as fibers may disrupt the stent.**

8.4 Delivery Procedure

Step	Action
1	Prepare vascular access site according to standard PTCA practice.
2	Pre-dilate the lesion/vessel with appropriate diameter balloon having a ratio of 1:1 with the diameter of the vessel. This step may be eliminated if direct stenting is performed.
3	Maintain neutral pressure on inflation device. Open rotating hemostatic valve to allow for easy passage of the stent. **Note:** If resistance is encountered, **do not force passage**. Resistance may indicate a problem and may result in damage to the stent if it is forced. Remove the system and examine.
4	Backload a 0.014 inch guidewire into the distal tip, holding the distal portion of the delivery system straight without any curving. Insert Stent Delivery System over guidewire through a large bore hemostatic valve adapter using conventional angioplasty techniques. **Make sure the hemostatic valve has a large bore and is fully open while passing the stent through.**
5	Ensure guiding catheter stability before advancing the Stent Delivery System into the coronary artery. Carefully advance the Stent Delivery System into the hub of the guiding catheter.
6	**Note:** If the physician encounters resistance to the Stent Delivery System prior to exiting the guiding catheter, **do not force passage**. Resistance may indicate a problem and may result in damage to the stent if it is forced. Maintain guidewire placement across the lesion and remove the Stent Delivery System as a single unit. (see Stent/System Removal – Precautions)
7	Advance delivery system over the guidewire to the target lesion under direct fluoroscopic visualization. Utilize the proximal and distal radiopaque markers on the balloon as a reference point. If the position of the stent is not optimal, it should be carefully repositioned or removed. (see Stent/ Delivery System Removal - Precautions) Expansion of the stent should not be undertaken if the stent is not properly positioned in the target lesion segment of the vessel.
8	Optimal stent placement requires the distal end of the stent to be placed approximately 1 mm beyond the distal end of the lesion.
9	Sufficiently tighten the rotating hemostatic valve. Stent is now ready to be deployed.

The safety and effectiveness of using mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters), or laser angioplasty catheters, to treat in-stent stenosis have not been established.

8. CLINICIAN USE INFORMATION

8.1 Inspection Prior to Use

Carefully inspect the sterile package before opening. It is not recommended that the product be used after the "Use By" date. If the integrity of the sterile package has been compromised prior to the product "Use By" date (e.g., damage of the package) contact your local Medtronic, Inc. Representative for return information. If the sterile package appears intact, carefully remove the system from the package and inspect for bends, kinks and other damage. Verify that the stent is located between the radiopaque markers. Do not use if any defects are noted.

8.2 Materials Required

Quantity	Material
	Appropriate guiding catheter. (see Table 1- Device Specifications)
1	20 cc syringe.
	Heparinized normal saline.
1	0.014 inch x 300 cm guidewire.
1	Rotating hemostatic valve.
	Contrast medium diluted 1:1 with heparinized normal saline.
1	Inflation device.
1	Torque device.
Optional	Three-way stopcock.

8.3 Preparation of Delivery System

Step	Action
1	Prepare the guiding catheter and guidewire according to the manufacturer's instructions. The Medtronic Driver Stent Delivery System is compatible with 0.014" guidewires. Refer to product labeling for specific guiding catheter compatibility.
2	Careful stent sizing is important to successful stenting. In general, the stent size should be chosen to match the diameter of the reference vessel and to correspond with the length of the lesion. Slight stent oversizing is preferable to undersizing. **Note:** The inflated balloon diameter measures slightly larger than the labeled stent diameter to allow for stent recoil following expansion.
3	Remove the stent delivery system from the package.
4	Attach the blunt end of a syringe to the distal end of the catheter and flush the Stent Delivery System until fluid exits from the guidewire entry/exit port.
5	Remove protective sheath covering from the stent/balloon. Special care must be taken not to handle the stent or in any way disrupt its placement on the balloon.
6	Inspect the stent to ensure it has not been damaged or displaced from its original position on the balloon. Verify that the stent is positioned between the proximal and distal balloon markers. **Note:** Should there be movement of or damage to the stent, do not use.
7	Flush Stent Delivery System guidewire lumen with heparinized normal saline until fluid exits the distal tip.

8	Fill a 20 cc syringe with 5 cc of contrast/heparinized normal saline mixture (1:1).
9	Attach to delivery system and apply negative pressure for 20-30 seconds.
10	Slowly release pressure to allow negative pressure to draw mixture into balloon lumen.
11	Detach syringe and leave a meniscus of mixture on the hub of the balloon lumen.
12	Prepare inflation device in standard manner and purge to remove all air from syringe and tubing.
13	Attach inflation device to catheter directly ensuring no bubbles remain at connection.
14	Leave on ambient pressure (neutral position). **Note: Do not pull negative pressure on inflation device after balloon preparation and prior to delivering the stent.**
15	Moisten the stent with heparinized normal saline by submerging the stent into a sterile bowl containing the solution. **Note: Do not use gauze sponges to wipe down the stent as fibers may disrupt the stent.**

8.4 Delivery Procedure

Step	Action
1	Prepare vascular access site according to standard PTCA practice.
2	Pre-dilate the lesion/vessel with appropriate diameter balloon having a ratio of 1:1 with the diameter of the vessel. This step may be eliminated if direct stenting is performed.
3	Maintain neutral pressure on inflation device. Open rotating hemostatic valve to allow for easy passage of the stent. **Note:** If resistance is encountered, **do not force passage**. Resistance may indicate a problem and may result in damage to the stent if it is forced. Remove the system and examine.
4	Backload a 0.014 inch guidewire into the distal tip, holding the distal portion of the delivery system straight without any curving. Insert Stent Delivery System over guidewire through a large bore hemostatic valve adapter using conventional angioplasty techniques. **Make sure the hemostatic valve has a large bore and is fully open while passing the stent through.**
5	Ensure guiding catheter stability before advancing the Stent Delivery System into the coronary artery. Carefully advance the Stent Delivery System into the hub of the guiding catheter.
6	**Note:** If the physician encounters resistance to the Stent Delivery System prior to exiting the guiding catheter, **do not force passage**. Resistance may indicate a problem and may result in damage to the stent if it is forced. Maintain guidewire placement across the lesion and remove the Stent Delivery System as a single unit. (see Stent/System Removal – Precautions)
7	Advance delivery system over the guidewire to the target lesion under direct fluoroscopic visualization. Utilize the proximal and distal radiopaque markers on the balloon as a reference point. If the position of the stent is not optimal, it should be carefully repositioned or removed. (see Stent/ Delivery System Removal - Precautions) Expansion of the stent should not be undertaken if the stent is not properly positioned in the target lesion segment of the vessel.
8	Optimal stent placement requires the distal end of the stent to be placed approximately 1 mm beyond the distal end of the lesion.
9	Sufficiently tighten the rotating hemostatic valve. Stent is now ready to be deployed.

8.5 Stent Deployment Procedure

Step	Action
1	Deploy stent by inflating balloon to nominal pressure to expand the stent. **Note:** Refer to product labeling and Table 5 for the proper stent inflation pressure. The Medtronic Driver Rapid Exchange Coronary Stent Delivery System may be reinflated beyond nominal, without repositioning, up to rated burst, to assure complete apposition of the stent to the artery wall. **Do not exceed Rated Burst Pressure (16 ATM). Do not expand the stent beyond 5.0 mm.**
2	Maintain inflation pressure for 15-30 seconds for full expansion of the stent.
3	**Note:** Under-expansion of the stent may result in stent movement. Care must be taken to properly size the stent to ensure the stent is in full contact with the arterial wall upon deflation of the balloon.

8.6 Removal Procedure

Step	Action
1	Deflate the balloon by pulling negative pressure on the inflation device. Allow adequate time, at least 15 seconds, for full balloon deflation. Longer stents may require more time for deflation.
2	Open the hemostatic valve to allow removal of the delivery system.
3	Maintain position of guiding catheter and guidewire to prevent it from being drawn into the vessel. Very slowly, withdraw the balloon from the stent maintaining negative suction, allowing movement of the myocardium to gently dislodge the balloon from the stent.
4	After removal of the delivery system, tighten the hemostatic valve.
5	Repeat angiography and visually assess the vessel and the stent for proper expansion.
6	A second balloon inflation may be required to insure optimal stent expansion. In such instances, the Medtronic Driver Stent Delivery System may be reinflated up to rated burst pressure (16 ATM), or a non-compliant, higher-pressure balloon of adequate size (the same size as the Stent Delivery System balloon or larger) and length may be used to accomplish this. **Note:** In smaller or diffusely diseased vessels, the use of high balloon inflation pressures may over-expand the vessel distal to the stent and could result in vessel dissection. **Do not exceed Rated Burst Pressure (16 ATM). Do not expand the Medtronic Driver stent beyond 5.0 mm.**
7	The final internal stent diameter should be equal to or slightly larger than the proximal and distal reference vessel diameters.
8	Repeat angiography to evaluate and determine procedure status or termination. **Note:** Should the need arise for placement of a second stent to adequately cover the lesion length, placement of the stent most distal in the artery should be done prior to placement of the proximal stent, if possible.
9	**Note:** Observation of the patient and angiographic evaluation of the stent site should be performed periodically within the first 30 minutes after stent placement. If stent placement is associated with the onset of thrombus or suspected thrombus in the region of the stented segment, intracoronary infusions of a thrombolytic agent is recommended.

8.7 Stent / Delivery System Removal Precautions

If removal of a stent system is required prior to deployment, ensure that the guide catheter is coaxially positioned relative to the stent system and cautiously withdraw the stent system into the guide catheter.

Should **unusual resistance** be felt **at any time** when withdrawing the stent towards the guide catheter, the Stent Delivery System and the guiding catheter **should be removed as a single unit**. This must be done under direct visualization with fluoroscopy.

When removing the Stent Delivery System and guiding catheter as a single unit:

- **Do not retract the Stent Delivery System into the guiding catheter.** Maintain guidewire placement across the lesion and carefully pull back the Stent Delivery System until the proximal balloon marker of the Stent Delivery System is aligned with the distal tip of the guiding catheter.
- The guiding catheter and the Stent Delivery System should be carefully removed from the coronary artery as a single unit.
- The system should be pulled back into the descending aorta toward the arterial sheath. As the distal end of the guiding catheter enters into the arterial sheath, the catheter will straighten, allowing safe withdrawal of the Stent Delivery System into the guiding catheter and the subsequent removal of the Stent Delivery System and the guiding catheter from the arterial sheath.

Failure to follow these steps and/or applying excessive force to the Stent Delivery System can potentially result in loss or damage to the stent and/or Stent Delivery System components such as the balloon.

Table 5. Medtronic Driver Stent Inner Diameter (mm) vs. Inflation Pressure (ATM)

	MEDTRONIC DRIVER STENT INNER DIAMETER (MM) Average Stent Inner Diameter (mm) Following Deployment:												
Stent Diameter	**6 ATM**	**7 ATM**	**8 ATM**	**9* ATM**	**10 ATM**	**11 ATM**	**12 ATM**	**13 ATM**	**14 ATM**	**15 ATM**	**16** ATM**	**17 ATM**	**18 ATM**
3.0mm	2.8	2.9	2.9	3.0	3.0	3.0	3.1	3.1	3.1	3.2	3.2	3.3	3.3
3.5mm	3.3	3.3	3.4	3.5	3.5	3.5	3.6	3.6	3.7	3.7	3.8	3.8	3.9
4.0mm	3.8	3.8	3.9	4.0	4.0	4.1	4.1	4.2	4.2	4.2	4.3	4.3	4.4

*Nominal Deployment Pressure (9 ATM)
Rated Burst Pressure. **DO NOT EXCEED.

Note: The nominal *in vitro* device specification does not take into account lesion resistance. Stent sizing should be confirmed angiographically.
Note: Do not expand the stent beyond 5.0 mm.
Note: Balloon pressures should be monitored during inflation. Do not exceed Rated Burst Pressure as specified on product label as this may result in a ruptured balloon with possible intimal damage and dissection.

9. PATIENT INFORMATION (UNITED STATES ONLY)

In addition to the Instructions for Use, the Medtronic Driver Rapid Exchange Coronary Stent System is packaged with additional specific information which includes:

- A Patient Guide which includes information on Medtronic, Inc., the implant procedure and Medtronic , Inc. coronary stents.

- A Coronary Stent Implant Card that includes both patient information, stent implant information and MRI guidelines. All patients will be instructed to keep this card in their possession at all times for procedure/stent identification. (Note: The Coronary Stent Implant Card is located in the back of the Patient Guide.)

Protected under one or more of the following U.S. Patents: 5,292,331; 5,674,278; 5,800,509; 5,836,965; 5,879,382; 5,891,190; 6,159,229; 6,190,358; 6,309,402; 6,344,053; 6,605,057 and other U.S. and foreign patents pending.

DISCLAIMER OF WARRANTY

NOTE: ALTHOUGH THE MEDTRONIC CORONARY STENT SYSTEM, HEREAFTER REFERRED TO AS "PRODUCT," HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, MEDTRONIC, INC., MEDTRONIC VASCULAR, INC. AND THEIR AFFILIATES (COLLECTIVELY, "MEDTRONIC") HAVE NO CONTROL OVER CONDITIONS UNDER WHICH THIS PRODUCT IS USED. MEDTRONIC, THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESSED AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. MEDTRONIC SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND MEDTRONIC TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

The exclusions and limitations set out above are not intended to and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected.

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Medtronic, Inc.
Minneapolis, MN 55432

Manufactured By:

Medtronic Ireland
Parkmore Business Park West
Galway, IRELAND

To Order:

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For Technical Information:

Medtronic, Inc.
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Fax: (800) 838-3103

PS 112613-01, Rev. A

Medtronic Driver

OVER-THE-WIRE CORONARY STENT SYSTEM

INSTRUCTIONS FOR USE

Medtronic Driver
OVER-THE-WIRE CORONARY STENT SYSTEM

Caution: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

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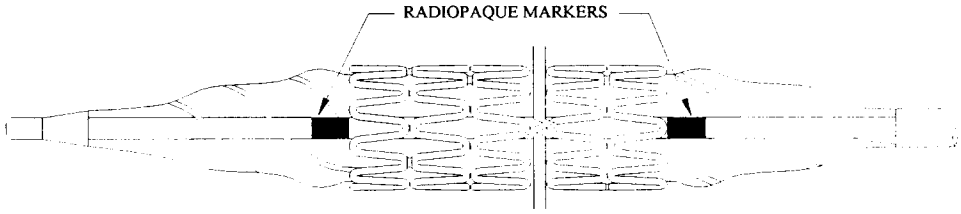
1. DEVICE DESCRIPTION

The Medtronic Driver Over-the-Wire Coronary Stent System consists of a balloon-expandable intracoronary stent premounted on a custom balloon delivery system. The balloon delivery system has two radiopaque markers to aid in the placement of the stent during fluoroscopy. The delivery system is compatible with 0.014" guidewires and has a useable length of 135 cm.
The Driver Coronary Stent is manufactured from a cobalt alloy. The coronary stents are formed from laser fused elements. The stents are provided in multiple lengths and diameters.



DRAWING FOR REFERENCE ONLY; DRAWING NOT TO SCALE

Figure 1. Medtronic Driver Graphic

Package contains one coronary stent premounted on a custom stent delivery system. Sterile, non-pyrogenic in unopened, undamaged packages. Intended for single use only. Do not resterilize. Sterilized by e-beam radiation. Store in a cool, dry, dark place. Use by the "Use By" date noted on the package.

CAUTION: Should there be damage to the package, do not use.

Table 1. Driver Coronary Stent Delivery System Specifications

Stent Diameter	Stent Lengths Available	Minimum Guiding Catheter Compatibility*	Stent Deployment Pressure	Rated Burst Pressure (RBP)	% Stent Free Area
3.0 mm	9,12,15,18,24, 30 mm	0.056 inch	9 atm	16 atm	81
3.5 mm	9,12,15,18,24, 30 mm	0.056 inch	9 atm	16 atm	83
4.0 mm	9,12,15,18,24, 30 mm	0.056 inch	9 atm	16 atm	85

* See manufacturer's specifications for (Fr.) equivalent.

2. INDICATIONS FOR USE

The Medtronic Driver Over-the-Wire Coronary Stent System is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete *de novo* or restenotic lesions with reference vessel diameters of 3.0 – 4.0 mm and ≤ 30 mm in length using direct stenting or pre-dilatation. Outcome beyond 270 days for this permanent implant is unknown at present.

3. CONTRAINDICATIONS

The Medtronic Driver Over-the-Wire Coronary Stent System is contraindicated for use in:

- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.
- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon.

4. WARNINGS AND PRECAUTIONS

(See also Individualization of Treatment.)

- Judicious selection of patients is necessary since the use of this device carries the associated risk of subacute thrombosis, vascular complications and/or bleeding events. Administration of appropriate anticoagulant, antiplatelet and coronary vasodilator therapy is critical to successful stent implantation and follow-up.

- Patients allergic to cobalt, chromium or nickel may suffer an allergic reaction to this implant.

- Only physicians who have received appropriate training should perform implantation of the stent.

- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.

- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized coronary stents is unknown at present.

- When multiple stents are required, stent materials should be of similar composition. Placing multiple stents of different materials in contact with each other may increase the potential for corrosion. Data obtained from *in vitro* corrosion tests using a F562 CoCr alloy stent (Medtronic Driver Coronary Stent) in combination with a 316L stainless steel alloy stent (Medtronic S7 Coronary Stent) do not suggest an increased risk of *in vivo* corrosion.

- If the physician encounters difficulty while trying to cross the lesion by direct stenting and determines the lesion to be uncrossable, this patient should be treated per predilatation practice. The stent (the same stent if undamaged) or a new stent of the same kind, should then be advanced and deployed with pre-dilatation.

4.1 Stent Handling – Precautions

- **For single use only**. Do not resterilize or reuse. Note product "Use By" date.
- **Do not remove stent from the Stent Delivery System** as removal may damage the stent and/or lead to stent embolization. The Medtronic Driver Over-the-Wire Coronary Stent System is intended to perform as a system. The Medtronic Driver Stent is not designed to be crimped onto another delivery device.
- Stent Delivery System should not be used in conjunction with any other stents.
- Special care must be taken not to handle or in any way disrupt the stent position on the delivery device. This is most important during catheter removal from packaging, placement over guidewire, and advancement through rotating hemostatic valve adapter and guiding catheter hub.
- Excessive manipulation, e.g., rolling the mounted stent, may cause dislodgement of the stent from the delivery balloon.
- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as it may cause uneven expansion and difficulty in deployment of the stent.

4.2 Stent Placement – Precautions

- **Do not prepare or pre-inflate the Stent Delivery System prior to stent deployment**, other than as directed. Use balloon purging technique described in section 9.3.2 Delivery System Preparation.
- Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stented portion, and may cause acute closure of the vessel requiring additional intervention (e.g., CABG, further dilatation, placement of additional stents, or other).
- When treating multiple lesions, the distal lesion should be initially stented, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent when placing the distal stent and reduces the chances for dislodging the proximal stent.
- Do not expand the stent if it is not properly positioned in the vessel (see section 9.7-Stent/System Removal – Precautions).
- Placement of the stent has the potential to compromise side branch patency.
- **Do not exceed Rated Burst Pressure as indicated on product label.** Balloon pressures should be monitored during inflation (see Compliance Chart - Table 4). Use of pressures higher than those specified on product label may result in a ruptured balloon and potential intimal damage and dissection.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the coronary vasculature and/or the vascular access site. Complications can include bleeding, hematoma or pseudoaneurysm.

4.3 Post-Implant– Precautions

Care must be exercised when **crossing a newly deployed stent** with an intravascular ultrasound (IVUS) catheter, a coronary guidewire, or a balloon catheter to avoid disrupting the stent geometry.

4.4 MRI Statement

The Driver Coronary Stent has been shown to be MRI safe immediately following implantation at a field strength of up to 1.5 Tesla, a maximum spatial gradient of 5.25 Tesla/meter (or 525 gauss/cm), gradient magnetic fields of 6.3 mT/m or less and a maximum whole body averaged specific absorption rate (SAR) of 4 W/kg for 15 minutes of MR imaging. MR imaging may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

5. OBSERVED ADVERSE EVENTS

The Medtronic Driver DeNovo and Restenotic Registry enrolled 298 patients in a non-randomized, multi-center study. These patients form the basis of the observed events reported in the following section.

5.1 Driver DeNovo and Restenotic Registry

A total of 298 patients were enrolled in a multi-center registry to evaluate the safety and efficacy of the Medtronic Driver Coronary Stent System for treatment of symptomatic coronary artery disease.

The primary endpoint of MACE at 180 days was compared to an objective performance criterion (OPC) of 15% based on a pooled MACE rate derived by pooling the data from the Bard XT Stent EXTRA RCT, Medtronic Micro Stent II SMART RCT, and Medtronic BeStent I (BEST) & BeStent II Registries.

Adverse events reported during the first six and nine months are shown in Table 2. A total of 25 of 298 patients (8.4%) who received the Medtronic Driver stent experienced one or more adverse events during the nine months of follow-up.

A total of 4 of the 298 (1.3%) patients who received the Driver stent died during the clinical study. These out-of-hospital deaths were all non-cardiac related: one secondary to ovarian cancer at 43 days post-procedure, one secondary to a brain tumor at 136 days post-procedure, one due to acute respiratory failure at 242 days post-procedure and one non-specified cancer death at 268 days post-procedure. There were no instances of stent thrombosis during the first 270 days. The incidence of vascular complications was 3.4% (10/298). The rate of bleeding complications was 2.3% (7/298). There were no (0/298) delivery or device failures reported.

Table 2. Principal Adverse Events Through 180 & 270 Days
Driver DeNovo and Restenotic Registry
%, (Number) [95% confidence interval)

Complication*	Medtronic Driver Stent (N=298) 180-Day Results	Medtronic Driver Stent (N=298) 270-Day Results
Adverse Event[§]	**7.7%** (23)[5.0%,11.4%]	**8.4%** (25)[5.5%,12.1%]
In-Hospital	**5.7%** (17)[3.4%,9.0%]	**5.7%** (17)[3.4%,9.0%]
Out-of-Hospital	**2.0%** (6)[0.7%,4.3%]	**2.7%** (8){1.2%,5.2%]
MACE	**5.7%** (17)[3.4%,9.0%]	**10.1%** (30) [6.9%,14.1%]
In-Hospital	**1.7%** (5)[0.5%,3.9%]	**1.7%** (5)[0.5%,3.9%]
Out-of-Hospital	**4.0%** (12)[2.1%,6.9%]	**8.4%** (25) [5.5%,12.1%]
Death	**0.7%** (2)[0.1%,2.4%]	**1.3%** (4) [0.4%, 3.4%]**
In-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Out-of-Hospital	**0.7%** (2)[0.1%,2.4%]	**1.3%** (4) [0.4%,3.4%]**
Q-wave MI	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
In-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Out-of-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Non Q-wave MI	**1.7%** (5)[0.5%,3.9%]	**1.7%** (5)[0.5%,3.9%]
In-Hospital	**1.7%** (5)[0.5%,3.9%]	**1.7%** (5)[0.5%,3.9%]
Out-of-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Target Lesion Revascularization	**3.4%** (10) [1.6%,6.1%]	**7.0%** (21) [4.4%, 10.6%}
In Hospital -PTCA	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
In Hospital-CABG	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Out-of-Hospital PTCA	**2.7%** (8)[1.2%,5.2%]	**6.4%** (19) [3.9%, 9.8%]
Out-of-Hospital CABG	**0.7%** (2) [0.1%,2.4%]	**0.7%** (2) [0.1%,2.4%]
Emergent CABG	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
In-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Out-of-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Stent Thrombosis	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
In-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Out-of-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Bleeding (procedural transfusion)	**2.3%** (7)[0.9%,4.8%]	**2.3%** (7)[0.9%,4.8%]
In-Hospital	**2.0%** (6)[0.7%,4.3%]	**2.0%** (6)[0.7%,4.3%]
Out-of-Hospital	**0.3%** (1)[0.0%,1.9%]	**0.3%** (1)[0.0%,1.9%]
CVA	**0.3%** (1)[0.0%,1.9%]	**0.3%** (1)[0.0%,1.9%]
In-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Out-of-Hospital	**0.3%** (1)[0.0%,1.9%]	**0.3%** (1)[0.0%,1.9%]
Vascular Complications	**3.4%** (10)[1.6%,6.1%]	**3.4%** (10)[1.6%,6.1%]
In-Hospital	**2.7%** (8)[1.2%,5.2%]	**2.7%** (8)[1.2%,5.2%]
Out-of-Hospital	**0.7%** (2)[0.1%,2.4%]	**0.7%** (2)[0.1%,2.4%]
Stent Delivery Failures	**0.0%** (0) [0.0%, 1.2%]	**0.0%** (0) [0.0%, 1.2%]

*Complications are based on patient totals. Seven patients had multiple adverse events: one patient had 3 vascular complications, four patients had 2 vascular complications), one patient had 1 non-Q MI and 1 bleeding. complication), and one patient had1 non-Q MI and 1 vascular complication.

[§]Adverse Event= Death, Q or Non-Q wave MI, Emergent CABG, Stent Thrombosis, CVA, Bleeding Complications, and Vascular Complications.
**All four deaths were non-cardiac.
Definitions for the terms used in Table 2 are found in the footnotes to Table 3.

5.2 Potential Adverse Events

Potential adverse events that may be associated with the use of a coronary stent in native coronary arteries (including those listed in Table 2) are listed below in order of severity:

- Death
- Emergency Coronary Artery Bypass Graft Surgery (CABG)
- Stroke/Cerebrovascular Accidents
- Cardiac tamponade
- Stent thrombosis or occlusion
- Total occlusion of coronary artery
- Acute myocardial infarction
- Restenosis of stented segments
- Perforation
- Arrhythmias, including ventricular fibrillation & ventricular tachycardia
- Dissection
- Emboli, distal (air, tissue or thrombotic emboli)
- Stent embolization
- Hemorrhage requiring transfusion
- Pseudoaneurysm, femoral
- Spasm
- Myocardial ischemia
- Hypotension/Hypertension
- Allergic reaction to drugs/contrast medium/stent material
- Peripheral ischemia
- Peripheral nerve injury
- Infection and pain at the insertion site
- Hematoma

6. CLINICAL TRIAL RESULTS

6.1 Driver DeNovo and Restenotic Registry

6.1.1 Purpose

The purpose of the Driver Registry was to evaluate the safety and efficacy of the Medtronic Driver stent for the treatment of single *de novo* or restenotic post-PTCA (non-stented) lesions in native coronary arteries.

6.1.2 Conclusions

The Driver Registry demonstrated the 180-day and 270-day safety and efficacy of the Driver stent for treatment of patients with *de novo* or restenotic lesions in native coronary arteries.

6.1.3 Design

A prospective, multi-center non-randomized study was conducted at 23 North American clinical sites enrolling 298 patients. Patients were 18 years of age or older with clinical evidence of ischemic heart disease or a positive functional study undergoing elective treatment for a single *de novo* or restenotic (post PTCA, non-stented) lesion in a native coronary artery. Eligible patients had visually estimated stenosis ≥ 50% and < 100% in a lesion ≤ 30 mm in length located in a major coronary artery or major side branch ≥ 3.0 mm and ≤ 4.0 mm in diameter.

The primary endpoint in the Driver DeNovo and Restenotic Registry was Major Adverse Cardiac Event (MACE) rate defined as the composite of death, Q wave and non-Q wave myocardial infarction, emergent bypass surgery, or target lesion revascularization (TLR) at 180 days. The primary endpoint was analyzed on an intent-to-treat basis, defined as patients who had the study device introduced into the guide catheter after determination that the subject and the target lesion met all inclusion criteria and none of the exclusion criteria.

The primary endpoint of MACE at 180 days was compared to an objective performance criterion (OPC) of 15% plus delta of 6%, based on a pooled MACE rate derived from the Bard XT Stent EXTRA RCT, Medtronic Micro Stent II SMART RCT, and Medtronic BeStent I (BEST) & BeStent II Registries. These studies had a range of 12.1% to 15.7% for MACE at 6 months compared to the Driver Registry 6 month MACE rate of 5.7% (17/298).

Secondary endpoints, (including acute success, target vessel failure (TVF) in hospital, at 14, 30, 180 and 270 days, clinically driven target lesion revascularization (TLR) at 180 and 270 days, binary angiographic restenosis (≥ 50% in-stent diameter stenosis) at 180 days in the 101 patient subset, late loss at 180 days and ischemic, bleeding and vascular complications) were analyzed on a per-protocol evaluable basis, defined as patients who had successful procedures and were available for follow-up.

All patients received the hospital's standard anti-coagulation/anti-platelet regimen for coronary stent implantation. The ACT was kept at therapeutic levels for Percutaneous Coronary Intervention per the hospital standard.

6.1.4 Demographics

Of the 298 patients enrolled, baseline demographics and clinical characteristics showed a mean age of 62.6 years (range 26 to 88 years), 68.1% (203/298) were men, 27.6% (82/297) had a history of diabetes mellitus, 75.9% (221/291) had hyperlipidemia requiring treatment, 28.8% (83/288) were current smokers and 68.4% (201/294) had hypertension requiring treatment.

6.1.5 Methods

Patients in the Driver DeNovo and Restenotic Registry underwent balloon angioplasty (1:1 balloon to artery ratio) after which a stent of the appropriate length and diameter was selected and deployed. The Medtronic Driver Coronary Stent System could be repressurized up to 16 atm to further dilate the stent to assure complete apposition of the stent to the artery wall. If needed, further inflations were performed with a non-compliant balloon with a balloon-to-artery ratio of 1:1.

The anticoagulation regimen administered to 100% of the patients included 325 mg/day of aspirin for at least 14 days; plus either ticlopidine, 250 mg b.i.d. or clopidogrel 75 mg q.d for 14 days. Glycoprotein IIbIIIa platelet inhibitors were administered to 32.6% (97/298) of the patients during the index procedure.

Clinical or telephone follow-up was conducted in-hospital, and at 14, 30, 180 and 270 days post-procedure. A subset of 27.8% (83/298) patients underwent follow-up angiography at the 180 day clinical follow-up. Data monitoring was conducted by Medtronic personnel. Angiographic films were analyzed and revascularizations were adjudicated by an independent Angiographic Core Laboratory. An independent Clinical Events Committee adjudicated all other primary endpoints and Major Adverse Cardiac Events.

6.1.6 Results

The Driver Registry 180 day TVF rate was 5.0% (15/298) and the TVF rate at 270 days was 9.7% (29/298). Adverse events for both time points are listed in Table 2 and the Principal Safety and Effectiveness results are presented in Table 3.

The primary endpoint of MACE at 180 days was compared to an objective performance criterion (OPC), based on a pooled MACE rate derived from previous AVE/Medtronic/USCI-Bard trials, of 15% plus delta of 6%. Specifically, the OPC of 15% as derived by pooling the data from the Bard XT Stent EXTRA RCT, Medtronic Micro Stent II SMART RCT, and Medtronic BeStent I (BEST) & BeStent II Registries.

A test of the null hypothesis that the observed Driver MACE rate of 5.7% (17/298) is greater or equal to 21% (15% OPC + delta of 6%), provided an Exact Test (one-sided) p-value less than 0.0001, leading to a rejection of this null hypothesis and signifying equivalency with the OPC rate (i.e., Driver MACE rate significantly less than 21%). In a test for superiority, the Driver MACE rate was significantly less than the OPC of 15% itself (p=0.0082).

Table 3. Principal Effectiveness and Safety Results - Medtronic Driver Stent

Efficacy Measures	**Medtronic Driver Stent (N=298)**
Post-Procedure In-Stent Minimal Lumen Diameter (mm) Mean±SD (N) Range (min,max)	 2.90±0.42 (284) (1.52,4.12)[2.85 , 2.94]
Procedure In-Stent Percent Diameter Stenosis (% DS) Mean±SD (N) Range (min,max)	 3.05±10.50 (284) (-32.31,41.12)[1.83 , 4.27]
Device Success	**100.0%** (298)[98.8%, 100%]
Procedure Success	**98.3%** (293)[96.1%, 99.5%]
Binary Restenosis Rate	**15.7%** (13/83)
TLR-free at 180 Days*	**96.2%** [94.7%, 97.7%]
TLR-free at 270 Days*	**91.2%** [86.5%, 95.8%]
TVR-free at 180 Days*	**95.5%** [93.5%, 96.9%]
TVR-free at 270 Days*	**90.0%** [85.1%, 95.0%]
TVF-free at 180 Days*	**92.8%** [90.8%, 94.8%]
TVF-free at 270 Days*	**88.3%** [83.1%, 93.6%]
Safety Measures & Other Clinical Events	**Medtronic Driver Stent (N=298)**
In-Hospital MACE (Death, QMI,NQMI, TLR, Emergent CABG)	**1.7%** (5)[0.5%, 3.9%]
Out-of-Hospital MACE (Death, QMI, NQMI, TLR, Emergent CABG)	**8.4%** (25) [5.5%,12.1%]
MACE to 180 days (Death, QMI, NQMI, TLR, Emergent CABG)	**5.7%** (17)[3.4%, 9.0%]
MACE to 270 days (Death, QMI, NQMI, TLR, Emergent CABG)	**10.1**% (30) [6.9%,14.1%]
TLR rate at 180 days	**3.4%** (10) [1.6%,6.1%]
TLR rate at 270 days	**7.0%** (21) [4.4%, 10.6%}
TVR rate at 180 days	**1.7%** (5)[0.5%,3.9%]
TVR rate at 270 days	**2.3%** (7)[0.9%, 4.8%]
TVF rate at 180 days	**6.7%** (20) [4.1%, 10.2%]
TVF rate at 270 days	**9.7%** (29) [6.6%, 13.7%]
Bleeding Complications	**2.3%** (7)[0.9%,4.8%]
CVA	**0.3%** (1)[0.0%,1.9%]
Vascular Complications	**3.4%** (10)[1.6%,6.1%]
Stent Thrombosis	**0.0%** (0)[0.0%,1.2%]

MACE: Major Adverse Cardiac Event (includes death, MI, and emergent CABG or target lesion revascularization).

TLR free: No target lesion revascularization.
TVR free: No target vessel revascularization.
TVF free: No death, any MI or target vessel revascularization.
Binary restenosis: 50% or greater in-stent diameter stenosis at the follow-up angiogram.
Stent Thrombosis: Stent thrombosis was defined as total thrombotic stent occlusion documented by angiography.
In-hospital major clinical event: death, MI, emergent CABG, repeat target lesion revascularization, stent thrombosis, or stroke prior to discharge, as determined by the independent Clinical Events Committee.
Out-of-hospital major clinical event: death, MI, emergent CABG, repeat target lesion revascularization, stent thrombosis, or stroke after discharge, as determined by the independent Clinical Events Committee.
Vascular complications; may include pseudoaneurysm, arteriovenous fistula, peripheral ischemia/nerve injury or vascular event requiring transfusion or surgical repair.
Bleeding complications: transfusions due to blood loss resulting from the percutaneous revascularization procedure.
CVA: sudden onset of vertigo, numbness, dysphasia, weakenss, visual field defects, dysarthria or other focal neurological deficits due to vascular lesions of the brain, such as hemorrhage, embolism, thrombosis, or rupturing aneurysm, that persists greater than 24 hours.
Device success: Attainment of <30% in-stent residual stenosis using the randomized treatment strategy only.
Procedure success: <50% stenosis in-stent (or in-lesion if no in-stent measurement available) and freedom from in-hospital major adverse cardiac events (death, MI, emergent CABG, or repeat target lesion revascularization).
*Survival estimates by Kaplan-Meier method; Standard Error estimates by Greenwood formula

6.2 PREDICT Trial

Based on acceptable performance in *de novo* lesions and the similarities in design and manufacture of the DRIVER Coronary Stent System to the Medtronic S670™ and Medtronic S7 Coronary Stent Systems, the following study, which evaluated direct stenting using the Medtronic S670 Coronary Stent, also supports the suitability of direct stenting for delivery of the Medtronic Driver Coronary Stent System.

The PREDICT Trial was a prospective, multi-center study using the S670™ OTW Coronary System randomized to either direct stenting or standard predilatation deployment technique. The study was conducted at 37 North American clinical sites and included a total of four hundred (400) randomized patients and sixteen (16) roll-in patients with *de novo* native coronary artery lesions. A clinical events committee adjudicated all major clinical events and clinically driven TLR.

6.2.1 Primary Endpoint

The primary endpoint in the PREDICT Trial was Major Adverse Cardiac Event (MACE) rate defined as the composite of death, Q wave and non-Q wave myocardial infarction, emergent coronary artery bypass surgery, or target lesion revascularization (TLR) at 14 days.

6.2.2 Patients Studied

The 399 patients (65.7% male) treated ranged in age from 29 to 87 years with an average of 64 ± 11.6 (mean ± SD) years. All patients presented with angina or a positive functional study and were undergoing elective single *de novo* lesion treatment in a native coronary artery. Eligible patients had visually estimated stenosis ≤ 15 mm in length in a major coronary artery or major side branch ≥ 3.0 mm and ≤ 4.0 mm in diameter. One patient withdrew consent after randomization but before investigational treatment was attempted.

6.2.3 Methods

Patients in the PREDICT Trial were randomized to either direct stenting (without predilatation) or standard pre-dilatation by balloon angioplasty (1:1 balloon to artery ratio) after which a stent system(s) of the appropriate length and diameter was selected and deployed. The Medtronic AVE S670™ OTW stent delivery system could be repressurized up to 16 atm to further dilate the stent to assure complete apposition of the stent to the artery wall. If needed, further inflations were performed with a non-compliant balloon with a balloon-to-artery ratio of 1:1. Clinical follow-up was conducted up to 6 months.

The anticoagulation regimen administered to 97% (389/399) of the patients at discharge was 325 mg aspirin and either 500 mg ticlopidine or 300 mg clopidogrel. The follow-up regimen administered to 83% (333/399) of the patients was 325 mg/day ASA for at least six month; ticlopidine 250 mg twice a day or clopidogrel 75 mg daily.

Clinical follow-up intervals for all treated PREDICT patients were 14 days, 30 days and 6 months. All patients underwent angiographic follow-up at 6 months for the PREDICT Trial. The study randomization was successful, as both treatment groups were demographically equivalent. All treated randomized patients were included in the intent-to-treat efficacy analysis. The principal effectiveness and safety for the PREDICT Trial for direct stenting versus predilatation are shown in table 4.

6.2.4 Conclusions

The success rate for the direct stenting arm was 92.0% (185/201). The sixteen patients who crossed over to the pre-dilatation arm were treated successfully. There were no statistically significant differences between the two arms with respect to Major Adverse Cardiac Events.

Table 4. Principal Effectiveness and Safety Results PREDICT Trial
S670 PREDICT Patients Treated (N = 399)

Efficacy Measures	Direct Stenting (N=198 Patients, N=201 Lesions)	Pre-Dilatation (N=201 Patients, N=203 Lesions)	All Randomized* (N=399 Patients, N=404 Lesions)	Relative Risk [95% C.I.]	Difference [95% C.I.]	P-value
Primary Device Success	92.0% (185 / 201)	96.6% (196 / 203)	94.3% (381 / 404)	0.95 [0.91,1.00]	-4.5% [-9.0%,0.0%]	0.056
Secondary Device Success	99.5% (200 / 201)	99.0% (200 / 202)	99.3% (400 / 403)	1.00 [0.99,1.02]	0.5% [-1.2%,2.2%]	1.000
Procedure Success	93.9% (186 / 198)	92.5% (185 / 200)	93.2% (371 / 398)	1.02 [0.96,1.07]	1.4% [-3.5%,6.4%]	0.691
Post-Procedure In-Lesion Minimal Lumen Diameter (MLD, in mm)						
Mean±SD (N)	2.54±0.55 (199)	2.56±0.50 (199)	2.55±0.52 (398)	N/A	-0.02 [-0.12,0.09]	0.739
Range (min,max)	(1.34,4.29)	(1.37,4.01)	(1.34,4.29)			
Post-Procedure In-Lesion Percent Diameter Stenosis (% DS)						
Mean±SD (N)	18.9%±9.8% (199)	18.3%±11.1% (199)	18.6%±10.5% (398)	N/A	0.6% [-1.5%,2.6%]	0.585
Range (min,max)	(1.5%,55.6%)	(-27.7%,54.2%)	(-27.7%,55.6%)			
Post-Procedure In-Stent Minimal Lumen Diameter (MLD, in mm)						
Mean±SD (N)	2.92±0.43 (199)	2.98±0.42 (199)	2.95±0.43 (398)	N/A	-0.06 [-0.14,0.03]	0.185
Range (min,max)	(1.84,4.30)	(2.10,4.34)	(1.84,4.34)			
Post-Procedure In-Stent Percent Diameter Stenosis (% DS)						
Mean±SD (N)	5.9%±9.4% (199)	4.5%±9.3% (199)	5.2%±9.4% (398)	N/A	1.4% [-0.5%,3.2%]	0.150
Range (min,max)	(-24.1%,35.8%)	(-34.7%,27.0%)	(-34.7%,35.8%)			
In-Lesion Acute Gain (mm)						
Mean±SD (N)	1.60±0.60 (199)	1.66±0.58 (199)	1.63±0.59 (398)	N/A	-0.06 [-0.18,0.06]	0.302
Range (min,max)	(0.11,3.74)	(0.06,2.97)	(0.06,3.74)			
In-Stent Acute Gain (mm)						
Mean±SD (N)	1.98±0.53 (199)	2.08±0.52 (199)	2.03±0.53 (398)	N/A	-0.10 [-0.20,0.00]	0.056
Range (min,max)	(0.77,3.74)	(0.34,3.59)	(0.34,3.74)			
In-Lesion Binary Restenosis Rate	26.5% (43 / 162)	25.8% (42 / 163)	26.2% (85 / 325)	N/A	0.8% [-8.8%,10.3%]	0.900
In-Stent Binary Restenosis Rate	20.4% (33 / 162)	20.9% (34 / 163)	20.6% (67 / 325)	N/A	-0.5% [-9.3%,8.3%]	1.000
TLR-free to 180 days†	80.2%	82.6%	81.5%	0.97 [0.78,1.21]	-2.4% [-20.0%,15.3%]	0.846
TVR-free to 180 days†	79.3%	79.3%	79.3%	1.00 [0.80,1.26]	0.0% [-18.1%,18.1%]	0.643
TVF-free to 180 days†	72.9%	72.5%	72.7%	1.01 [0.77,1.32]	0.4% [-19.4%,20.1%]	0.677
MACE-free to 180 days†	73.8%	74.5%	74.1%	0.99 [0.76,1.29]	-0.7% [-20.2%,18.9%]	0.770
Safety Measures and Other Clinical Events						
In-Hospital MACE	5.6% (11 / 198)	7.0% (14 / 201)	6.3% (25 / 399)	0.80 [0.37,1.71]	-1.4% [-6.2%,3.3%]	0.681
Out-of-Hospital MACE to 14 days	0.5% (1 / 198)	0.5% (1 / 201)	0.5% (2 / 399)	1.02 [0.06,16.17]	0.0% [-1.4%,1.4%]	1.000
MACE to 14 days	6.1% (12 / 198)	7.5% (15 / 201)	6.8% (27 / 399)	0.81 [0.39,1.69]	-1.4% [-6.3%,3.5%]	0.691
Out-of-Hospital MACE to 180 days	13.1% (26 / 198)	13.9% (28 / 201)	13.5% (54 / 399)	0.94 [0.57,1.55]	-0.8% [-7.5%,5.9%]	0.884
MACE to 180 days	18.7% (37 / 198)	19.4% (39 / 201)	19.0% (76 / 399)	0.96 [0.64,1.44]	-0.7% [-8.4%,7.0%]	0.899
Abrupt Closure to 180 days	0.0% (0 / 198)	1.5% (3 / 201)	0.8% (3 / 399)	0.00 [—,—]	-1.5% [-3.2%,0.2%]	0.248
Subacute Closure to 180 days	0.0% (0 / 198)	0.5% (1 / 201)	0.3% (1 / 399)	0.00 [—,—]	-0.5% [-1.5%,0.5%]	1.000
Stent Thrombosis to 180 days	0.5% (1 / 198)	0.5% (1 / 201)	0.5% (2 / 399)	1.02 [0.06,16.17]	0.0% [-1.4%,1.4%]	1.000
CVA to 180 days	0.0% (0 / 198)	0.0% (0 / 201)	0.0% (0 / 399)	— [—,—]	0.0% [—,—]	N/A
Bleeding Complications to 180 days	1.5% (3 / 198)	1.0% (2 / 201)	1.3% (5 / 399)	1.52 [0.26,8.91]	0.5% [-1.7%,2.7%]	0.684
Vascular Complications to 180 days	7.1% (14 / 198)	4.0% (8 / 201)	5.5% (22 / 399)	1.78 [0.77,4.09]	3.1% [-1.4%,7.6%]	0.194

†. One patient withdrew consent after randomization but before the investigational treatment was attempted and was deregistered.

Primary Device Success = The attainment of a <50% residual in-stent (or in-lesion in the absence of in-stent) stenosis (by QCA) of the target site using the assigned treatment strategy alone, (i.e. only the Medtronic AVE S670™ stent without pre-dilatation if so randomized) during the index catheterization. If QCA was not available, the visual estimate of diameter stenosis was used. Post-dilatation with a high pressure or larger balloon was considered part of the treatment strategy for both arms, but tracked as to frequency. The need for pre-dilatation in patients randomized to direct stenting arm was considered a primary device failure and use of other brands of stents besides the Medtronic AVE S670™.

Secondary Device Success = The attainment of a <50% residual in-stent (or in-lesion in the absence of in-stent) stenosis (by QCA) of the target site using any strategy (including stent withdrawal, pre-dilatation or pre-treatment with another device, and a repeat attempt at stent implantation). If QCA was not available, the visual estimate of diameter stenosis was used. Post-dilatation with a high pressure or larger balloon was considered part of the treatment strategy for both arms, but tracked as to frequency.

Procedure Success = The attainment of a <50% in-stent (or in-lesion in the absence of in-stent) residual stenosis (by QCA) at the target site using any strategy and freedom from Major Adverse Cardiac Events prior to hospital discharge. If QCA was not available, the visual estimate of diameter stenosis was used.

In-Hospital MACE = Death, Q wave or non-Q wave MI, emergent CABG, or target lesion revascularization prior to discharge as determined by the independent Clinical Events Committee.

Out-of-Hospital MACE = Death, Q wave or non-Q wave MI, emergent CABG, or target lesion revascularization from hospital discharge through the 180-day contact, as determined by the independent Clinical Events Committee.

TLR-free = No target lesion revascularization.

TVR-free = No target vessel revascularization.

TVF-free = No death, MI, or target vessel revascularization.

Footnotes are continued on the following page.

MACE-free = No death, MI, emergent CABG, or target lesion revascularization.
Abrupt Closure = Occurrence of new severely reduced flow (TIMI grade 0 or 1) within the target vessel that persisted and required rescue by a non-assigned treatment strategy, or resulted in MI or death.
Subacute Closure = Abrupt closure that occurred after the index procedure was completed and within 30 days of the index procedure.
Stent Thrombosis = Angiographic thrombus or subacute closure within the stented vessel, or any death not attributed to a non-cardiac cause in the absence of documented angiographic stent patency within the first 30 days.
CVA = Acute neurological deficits recorded by the clinical sites that persisted >24 hours.
Bleeding Complications = Defined as transfusions of blood products due to blood loss from the percutaneous revascularization procedure.
Vascular Complications = Defined as hematoma >4 cm, false aneurysm, AV fistula, retroperitoneal bleed, peripheral ischemia/nerve injury, procedure related transfusion or vascular surgical repair.
Acute Gain = Acute gain was defined as the immediate dimensional change in minimal luminal diameter (in mm) that occurred as a result of the procedure, measured by quantitative coronary angiography based on data interpolated from two orthogonal views at baseline and after the final post dilatation.

7. PATIENT SELECTION AND TREATMENT

7.1 Individualization of Treatment

The risks and benefits described above should be carefully considered for each patient before use of the Medtronic Driver Over-the-Wire Coronary Stent System. Patient selection factors to be assessed should include a judgment regarding risk of prolonged anticoagulation. Stenting should be generally avoided in those patients at heightened risk of bleeding (e.g., those patients with recently active gastritis or peptic ulcer disease) (see Contraindications).

Co-morbidities that increase the risk of poor initial results or the risks of emergency referral for bypass surgery (diabetes mellitus, renal failure, and severe obesity) should be reviewed.

Thrombosis following stent implantation is affected by several baseline angiographic and procedural factors. These include vessel diameter less than 3.0 mm, intra-procedural thrombosis, poor distal flow, and/or dissection following stent implantation. In patients that have undergone coronary stenting, the persistence of a thrombus or dissection is considered a marker for subsequent thrombotic occlusion. These patients should be monitored very carefully during the first month after stent implantation.

7.2 Use in Special Populations

The safety and effectiveness of the Medtronic Driver Over-the-Wire Coronary Stent System have not been established in:

- Patients with **unresolved vessel thrombus at the lesion site**.
- Patients with coronary artery **reference vessel diameters < 3.0 mm**.
- Patients with **lesions located in the unprotected left main coronary artery, ostial lesions**, or **lesions located at a bifurcation**.
- Patients with diffuse disease or **poor outflow distal** to the identified lesions.
- Patients with recent **acute myocardial infarction** where there is evidence of thrombus or poor flow.
- Patients with **more than two overlapping stents** due to risk of thrombosis or poor flow.
- Patients beyond the **nine month follow-up** period

The safety and effectiveness of using mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters), or laser angioplasty catheters, to treat in-stent stenosis have not been established.

8. CLINICIAN USE INFORMATION

8.1 Inspection Prior to Use

Carefully inspect the sterile package before opening. It is not recommended that the product be used after the "Use By" date. If the integrity of the sterile package has been compromised prior to the product "Use By" date (e.g., damage of the package) contact your local Medtronic, Inc. Representative for return information. If the sterile package appears intact, carefully remove the system from the package and inspect for bends, kinks and other damage. Verify that the stent is located between the radiopaque markers. Do not use if any defects are noted.

8.2 Materials Required

Quantity	Material
	Appropriate guiding catheter. (see Table 1- Device Specifications)
1	20 cc syringe.
	Heparinized normal saline.
1	0.014 inch x 300 cm guidewire.
1	Rotating hemostatic valve.
	Contrast medium diluted 1:1 with heparinized normal saline.
1	Inflation device.
1	Torque device.
Optional	Three-way stopcock.

8.3 Preparation of Delivery System

Step	Action
1	Prepare the guiding catheter and guidewire according to the manufacturer's instructions. The Medtronic Driver Stent Delivery System is compatible with 0.014" guidewires. Refer to product labeling for specific guiding catheter compatibility.
2	Careful stent sizing is important to successful stenting. In general, the stent size should be chosen to match the diameter of the reference vessel and to correspond with the length of the lesion. Slight stent oversizing is preferable to undersizing. **Note:** The inflated balloon diameter measures slightly larger than the labeled stent diameter to allow for stent recoil following expansion.
3	Remove the stent delivery system from the package.
4	Remove protective sheath covering from the stent/balloon. Special care must be taken not to handle the stent or in any way disrupt its placement on the balloon.
5	Inspect the stent to assure it has not been damaged or displaced from its original position on the balloon. Verify that the stent is positioned between the proximal and distal balloon markers. **Note:** Should there be movement of or damage to the stent, do not use.
6	Flush Stent Delivery System guidewire lumen with heparinized normal saline until fluid exits the distal tip.
7	Fill a 20 cc syringe with 5 cc of contrast/heparinized normal saline mixture (1:1).
8	Attach to delivery system and apply negative pressure for 20-30 seconds.
9	Slowly release pressure to allow negative pressure to draw mixture into balloon lumen.
10	Detach syringe and leave a meniscus of mixture on the hub of the balloon lumen.
11	Prepare inflation device in standard manner and purge to remove all air from syringe and tubing.

12	Attach inflation device to catheter directly ensuring no bubbles remain at connection.
13	Leave on ambient pressure (neutral position). **Note: Do not pull negative pressure on inflation device after balloon preparation and prior to delivering the stent.**
14	Moisten the stent with heparinized normal saline by submerging the stent into a sterile bowl containing the solution. **Note: Do not use gauze sponges to wipe down the stent as fibers may disrupt the stent.**

8.4 Delivery Procedure

Step	Action
1	Prepare vascular access site according to standard PTCA practice.
2	Pre-dilate the lesion/vessel with appropriate diameter balloon having a ratio of 1:1 with the diameter of the vessel. This step may be eliminated if direct stenting is performed.
3	Maintain neutral pressure on inflation device. Open rotating hemostatic valve to allow for easy passage of the stent. **Note:** If resistance is encountered, **do not force passage**. Resistance may indicate a problem and may result in damage to the stent if it is forced. Remove the system and examine.
4	Ensure guiding catheter stability before advancing the Stent Delivery System into the coronary artery. Carefully advance the Stent Delivery System into the hub of the guiding catheter.
5	**Note:** If the physician encounters resistance to the Stent Delivery System prior to exiting the guiding catheter, **do not force passage**. Resistance may indicate a problem and may result in damage to the stent if it is forced. Maintain guidewire placement across the lesion and remove the Stent Delivery System as a single unit. (see Stent/System Removal – Precautions)
6	Advance delivery system over the guidewire to the target lesion under direct fluoroscopic visualization. Utilize the proximal and distal radiopaque markers on the balloon as a reference point. If the position of the stent is not optimal, it should be carefully repositioned or removed. (see Stent/ Delivery System Removal - Precautions) Expansion of the stent should not be undertaken if the stent is not properly positioned in the target lesion segment of the vessel.
7	Optimal stent placement requires the distal end of the stent to be placed approximately 1 mm beyond the distal end of the lesion.
8	Sufficiently tighten the rotating hemostatic valve. Stent is now ready to be deployed.

8.5 Stent Deployment Procedure

Step	Action
1	Deploy stent by inflating balloon to nominal pressure to expand the stent. **Note:** Refer to product labeling and Table 5 for the proper stent inflation pressure. The Medtronic Driver Over-the-Wire Coronary Stent Delivery System may be reinflated beyond nominal, without repositioning, up to rated burst, to assure complete apposition of the stent to the artery wall. **Do not exceed Rated Burst Pressure (16 ATM). Do not expand the stent beyond 5.0 mm.**
2	Maintain inflation pressure for 15-30 seconds for full expansion of the stent.
3	**Note:** Under-expansion of the stent may result in stent movement. Care must be taken to properly size the stent to ensure the stent is in full contact with the arterial wall upon deflation of the balloon.

8.6 Removal Procedure

Step	Action
1	Deflate the balloon by pulling negative pressure on the inflation device. Allow adequate time, at least 15 seconds, for full balloon deflation. Longer stents may require more time for deflation.

2	Open the hemostatic valve to allow removal of the delivery system.
3	Maintain position of guiding catheter and guidewire to prevent it from being drawn into the vessel. Very slowly, withdraw the balloon from the stent maintaining negative suction, allowing movement of the myocardium to gently dislodge the balloon from the stent.
4	After removal of the delivery system, tighten the hemostatic valve.
5	Repeat angiography and visually assess the vessel and the stent for proper expansion.
6	A second balloon inflation may be required to ensure optimal stent expansion. In such instances, the Medtronic Driver Stent Delivery System may be reinflated up to rated burst pressure (16 ATM), or a non-compliant, higher-pressure balloon of adequate size (the same size as the Stent Delivery System balloon or larger) and length may be used to accomplish this. **Note:** In smaller or diffusely diseased vessels, the use of high balloon inflation pressures may over-expand the vessel distal to the stent and could result in vessel dissection. **Do not exceed Rated Burst Pressure (16 ATM). Do not expand the Medtronic Driver stent beyond 5.0 mm.**
7	The final internal stent diameter should be equal to or slightly larger than the proximal and distal reference vessel diameters.
8	Repeat angiography to evaluate and determine procedure status or termination. **Note:** Should the need arise for placement of a second stent to adequately cover the lesion length, placement of the stent most distal in the artery should be done prior to placement of the proximal stent, if possible.
9	**Note:** Observation of the patient and angiographic evaluation of the stent site should be performed periodically within the first 30 minutes after stent placement. If stent placement is associated with the onset of thrombus or suspected thrombus in the region of the stented segment, intracoronary infusions of a thrombolytic agent is recommended.

8.7 Stent / Delivery System Removal Precautions

If removal of a stent system is required prior to deployment, ensure that the guide catheter is coaxially positioned relative to the stent system and cautiously withdraw the stent system into the guide catheter.

Should **unusual resistance** be felt **at any time** when withdrawing the stent towards the guide catheter, the Stent Delivery System and the guiding catheter **should be removed as a single unit**. This must be done under direct visualization with fluoroscopy.

When removing the Stent Delivery System and Guiding Catheter as a single unit:

- **Do not retract the Stent Delivery System into the guiding catheter.** Maintain guidewire placement across the lesion and carefully pull back the Stent Delivery System until the proximal balloon marker of the Stent Delivery System is aligned with the distal tip of the guiding catheter.

- The guiding catheter and the Stent Delivery System should be carefully removed from the coronary artery as a single unit.

- The system should be pulled back into the descending aorta toward the arterial sheath. As the distal end of the guiding catheter enters into the arterial sheath, the catheter will straighten, allowing safe withdrawal of the Stent Delivery System into the guiding catheter and the subsequent removal of the Stent Delivery System and the guiding catheter from the arterial sheath.

Failure to follow these steps and/or applying excessive force to the Stent Delivery System can potentially result in loss or damage to the stent and/or Stent Delivery System components such as the balloon.

Table 5. Medtronic Driver Stent Inner Diameter (mm) vs. Inflation Pressure (ATM)

	MEDTRONIC DRIVER STENT INNER DIAMETER (MM) Average Stent Inner Diameter (mm) Following Deployment:												
Stent Diameter	6 ATM	7 ATM	8 ATM	9* ATM	10 ATM	11 ATM	12 ATM	13 ATM	14 ATM	15 ATM	16** ATM	17 ATM	18 ATM
3.0mm	2.8	2.9	2.9	3.0	3.0	3.0	3.1	3.1	3.1	3.2	3.2	3.3	3.3
3.5mm	3.3	3.3	3.4	3.5	3.5	3.5	3.6	3.6	3.7	3.7	3.8	3.8	3.9
4.0mm	3.8	3.8	3.9	4.0	4.0	4.1	4.1	4.2	4.2	4.2	4.3	4.3	4.4

*Nominal Deployment Pressure (9 ATM)
Rated Burst Pressure. **DO NOT EXCEED.

Note: The nominal *in vitro* device specification does not take into account lesion resistance. Stent sizing should be confirmed angiographically.
Note: Do not expand the stent beyond 5.0 mm.
Note: Balloon pressures should be monitored during inflation. Do not exceed Rated Burst Pressure as specified on product label as this may result in a ruptured balloon with possible intimal damage and dissection.

9. PATIENT INFORMATION (UNITED STATES ONLY)

In addition to the Instructions for Use, the Medtronic Driver Over-the-Wire Coronary Stent System is packaged with additional specific information which includes:

- A Patient Guide which includes information on Medtronic, Inc., the implant procedure and Medtronic, Inc. coronary stents.
- A Coronary Stent Implant Card that includes both patient information, stent implant information and MRI guidelines. All patients will be instructed to keep this card in their possession at all times for procedure/stent identification. (Note: The Coronary Stent Implant Card is located in the back of the Patient Guide.)

Protected under one or more of the following U.S. Patents: 5,292,331; 5,674,278; 5,800,509; 5,836,965; 5,879,382; 5,891,190; 6,159,229; 6,190,358; 6,309,402; 6,344,053; 6,605,057 and other U.S. and foreign patents pending.

DISCLAIMER OF WARRANTY

NOTE: ALTHOUGH THE MEDTRONIC CORONARY STENT SYSTEM, HEREAFTER REFERRED TO AS "PRODUCT," HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, MEDTRONIC, INC., MEDTRONIC VASCULAR, INC. AND THEIR AFFILIATES (COLLECTIVELY, "MEDTRONIC") HAVE NO CONTROL OVER CONDITIONS UNDER WHICH THIS PRODUCT IS USED. MEDTRONIC, THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESSED AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. MEDTRONIC SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND MEDTRONIC TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

The exclusions and limitations set out above are not intended to and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected.

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PS 112611-01, Rev. A

Medtronic Driver

MULTI-EXCHANGE CORONARY STENT SYSTEM

INSTRUCTIONS FOR USE

Medtronic Driver
MULTI-EXCHANGE CORONARY STENT SYSTEM

Caution: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

Table of Contents

1. DEVICE DESCRIPTION

The Medtronic Driver MX Coronary Stent System includes:

- A pre-mounted cobalt alloy stent.
- A sheathless, extended pressure coronary stent system providing symmetrical stent deployment utilizing an extended pressure balloon.
- A movable Z component on the proximal shaft which facilitates loading and unloading of the guidewire into or from the wire lumen as the Z component moves along the proximal shaft. Allows utilization of a short guidewire while providing the option of wire interchange during device tracking.
- Two radiopaque (Platinum/Iridium) markers embedded in the inner shaft beneath the balloon, proximal and distal to the stent. The markers are visible under fluoroscopy.
- One flushing cannula.

The Medtronic Driver MX Coronary Stent System can be re-inflated to the rated burst pressure (RBP), without moving the placement of the balloon within the stent, to optimize stent apposition.

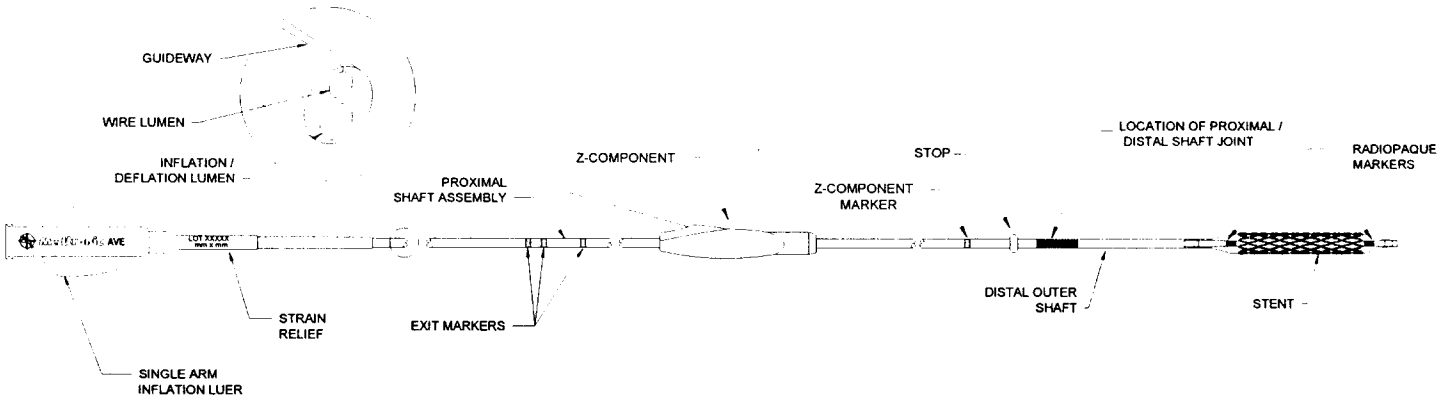


Figure 1. Medtronic Driver Multi-Exchange Delivery System

Package contains one coronary stent premounted on a custom stent delivery system. Sterile, non-pyrogenic in unopened, undamaged packages. Intended for single use only. Do not resterilize. Sterilized by e-beam radiation. Store in a cool, dry, dark place. Use by the "Use By" date noted on the package.

CAUTION: Should there be damage to the package, do not use.

Table 1. Driver Coronary Stent Delivery System Specifications

Stent Diameter	Stent Lengths Available	Minimum Guiding Catheter Compatibility*	Stent Deployment Pressure	Rated Burst Pressure (RBP)	% Stent Free Area
3.0 mm	9,12,15,18,24, 30 mm	0.064 inch	9 atm	16 atm	81
3.5 mm	9,12,15,18,24, 30 mm	0.064 inch	9 atm	16 atm	83
4.0 mm	9,12,15,18,24, 30 mm	0.064 inch	9 atm	16 atm	85

* See manufacturer's specifications for (Fr.) equivalent.

2. INDICATIONS FOR USE

The Medtronic Driver Multi-Exchange Coronary Stent System is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete *denovo* or restenotic lesions with reference vessel diameters of 3.0 – 4.0 mm and ≤ 30 mm in length using direct stenting or pre-dilatation. Outcome beyond 270 days for this permanent implant is unknown at present.

3. CONTRAINDICATIONS

The Medtronic Driver Multi-Exchange Coronary Stent System is contraindicated for use in:

- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.
- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon.

4. WARNINGS AND PRECAUTIONS

(See also Individualization of Treatment.)

- Judicious selection of patients is necessary since the use of this device carries the associated risk of subacute thrombosis, vascular complications and/or bleeding events. Administration of appropriate anticoagulant, antiplatelet and coronary vasodilator therapy is critical to successful stent implantation and follow-up.

- Patients allergic to cobalt, chromium or nickel may suffer an allergic reaction to this implant.

- Only physicians who have received appropriate training should perform implantation of the stent.

- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.

- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized coronary stents is unknown at present.

- When multiple stents are required, stent materials should be of similar composition. Placing multiple stents of different materials in contact with each other may increase the potential for corrosion. Data obtained from *in vitro* corrosion tests using a F562 CoCr alloy stent (Medtronic Driver Coronary Stent) in combination with a 316L stainless steel alloy stent (Medtronic S7 Coronary Stent) does not suggest an increased risk of *in vivo* corrosion.

- If the physician encounters difficulty while trying to cross the lesion by direct stenting and determines the lesion to be uncrossable, this patient should be treated per predilatation practice. The stent (the same stent if undamaged) or a new stent of the same kind, should then be advanced and deployed with pre-dilatation.

4.1 Stent Handling – Precautions

- **For single use only**. Do not resterilize or reuse. Note product "Use By" date.

- **Do not remove stent from the Stent Delivery System** as removal may damage the stent and/or lead to stent embolization. The Medtronic Driver Multi-Exchange Coronary Stent System is intended to perform as a system. The Medtronic Driver Stent is not designed to be crimped onto another delivery device.

- Stent Delivery System should not be used in conjunction with any other stents.

- Special care must be taken not to handle or in any way disrupt the stent position on the delivery device. This is most important during catheter removal from packaging, placement over guidewire, and advancement through rotating hemostatic valve adapter and guiding catheter hub.

- Excessive manipulation, e.g., rolling the mounted stent, may cause dislodgement of the stent from the delivery balloon.

- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as it may cause uneven expansion and difficulty in deployment of the stent.

4.2 Stent Placement – Precautions

- **Do not prepare or pre-inflate the Stent Delivery System prior to stent deployment**, other than as directed. Use balloon purging technique described in section 9.3.2-Delivery System Preparation.

- Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stented portion, and may cause acute closure of the vessel requiring additional intervention (e.g., CABG, further dilatation, placement of additional stents, or other).

- When treating multiple lesions, the distal lesion should be initially stented, followed by stenting of the proximal lesion. Stenting in this order obviates the need to cross the proximal stent when placing the distal stent and reduces the chances for dislodging the proximal stent.

- Do not expand the stent if it is not properly positioned in the vessel (see section 9.9-Stent/System Removal – Precautions).

- Placement of the stent has the potential to compromise side branch patency.

- **Do not exceed Rated Burst Pressure as indicated on product label.** Balloon pressures should be monitored during inflation (see Compliance Chart - Table 4). Use of pressures higher than those specified on product label may result in a ruptured balloon and potential intimal damage and dissection.

- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the coronary vasculature and/or the vascular access site. Complications can include bleeding, hematoma or pseudoaneurysm.

4.3 Post-Implant– Precautions

- Care must be exercised when **crossing a newly deployed stent** with an intravascular ultrasound (IVUS) catheter, a coronary guidewire, or a balloon catheter to avoid disrupting the stent geometry.

4.4 MRI Statement

The Driver Coronary Stent has been shown to be MRI safe immediately following implantation at a field strength of up to 1.5 Tesla, a maximum spatial gradient of 5.25 Tesla/meter (or 525 gauss/cm), gradient magnetic fields of 6.3 mT/m or less and a maximum whole body averaged specific absorption rate (SAR) of 4 W/kg for 15 minutes of MR imaging. MR imaging may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

5. OBSERVED ADVERSE EVENTS

The Medtronic Driver DeNovo and Restenotic Registry enrolled 298 patients in a non-randomized, multi-center study. These patients form the basis of the observed events reported in the following section.

5.1 Driver DeNovo and Restenotic Registry

A total of 298 patients were enrolled in a multi-center registry to evaluate the safety and efficacy of the Medtronic Driver Coronary Stent System for treatment of symptomatic coronary artery disease.

The primary endpoint of MACE at 180 days was compared to an objective performance criterion (OPC) of 15% based on a pooled MACE rate derived by pooling the data from the Bard XT Stent EXTRA RCT, Medtronic Micro Stent II SMART RCT, and Medtronic BeStent I (BEST) & BeStent II Registries.
Adverse events reported during the first six months are shown in Table 2. A total of 25 of 298 patients (8.4%) who received the Medtronic Driver stent experienced one or more adverse events during the first six months of follow-up.

A total of 4 of the 298 patients (1.3%) who received the Driver stent died during the clinical study. These out-of-hospital deaths were all non-cardiac related: one secondary to ovarian cancer at 43 days post-procedure, one secondary to a brain tumor at 136 days post-procedure, one due to acute respiratory failure at 242 days post-procedure and one non-specified cancer death at 268 days post-

procedure. There were no instances of stent thrombosis during the first 270 days. The incidence of vascular complications was 3.4% (10/298). The rate of bleeding complications was 2.3% (7/298).

There were no (0/298) delivery or device failures reported.

The primary endpoint of MACE at 180 days was compared to an objective performance criterion (OPC), based on a pooled MACE rate derived from previous AVE/Medtronic/USCI-Bard trials, of 15% plus delta of 6%. Specifically, the OPC of 15% as derived by pooling the data from the Bard XT Stent EXTRA RCT, Medtronic Micro Stent II SMART RCT, and Medtronic BeStent I (BEST) & BeStent II Registries. These studies had a range of 12.1% to 15.7% for MACE at 6 months.

Table 2. Principal Adverse Events Through 180 & 270 Days
Driver DeNovo and Restenotic Registry
%, (Number) [95% confidence interval)

Complication*	Medtronic Driver Stent (N=298) 180-Day Results	Medtronic Driver Stent (N=298) 270-Day Results
Adverse Event[§]	**7.7%** (23)[5.0%,11.4%]	**8.4%** (25)[5.5%,12.1%]
In-Hospital	**5.7%** (17)[3.4%,9.0%]	**5.7%** (17)[3.4%,9.0%]
Out-of-Hospital	**2.0%** (6)[0.7%,4.3%]	**2.7%** (8){1.2%,5.2%]
MACE	**5.7%** (17)[3.4%,9.0%]	**10.1%** (30) [6.9%,14.1%]
In-Hospital	**1.7%** (5)[0.5%,3.9%]	**1.7%** (5)[0.5%,3.9%]
Out-of-Hospital	**4.0%** (12)[2.1%,6.9%]	**8.4%** (25) [5.5%,12.1%]
Death	**0.7%** (2)[0.1%,2.4%]	**1.3%** (4) [0.4%, 3.4%]**
In-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Out-of-Hospital	**0.7%** (2)[0.1%,2.4%]	**1.3%** (4) [0.4%,3.4%]**
Q-wave MI	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
In-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Out-of-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Non Q-wave MI	**1.7%** (5)[0.5%,3.9%]	**1.7%** (5)[0.5%,3.9%]
In-Hospital	**1.7%** (5)[0.5%,3.9%]	**1.7%** (5)[0.5%,3.9%]
Out-of-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Target Lesion Revascularization	**3.4%** (10) [1.6%,6.1%]	**7.0%** (21) [4.4%, 10.6%}
In Hospital -PTCA	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
In Hospital-CABG	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Out-of-Hospital PTCA	**2.7%** (8)[1.2%,5.2%]	**6.4%** (19) [3.9%, 9.8%]
Out-of-Hospital CABG	**0.7%** (2) [0.1%,2.4%]	**0.7%** (2) [0.1%,2.4%]
Emergent CABG	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
In-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Out-of-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Stent Thrombosis	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
In-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Out-of-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Bleeding (procedural transfusion)	**2.3%** (7)[0.9%,4.8%]	**2.3%** (7)[0.9%,4.8%]
In-Hospital	**2.0%** (6)[0.7%,4.3%]	**2.0%** (6)[0.7%,4.3%]
Out-of-Hospital	**0.3%** (1)[0.0%,1.9%]	**0.3%** (1)[0.0%,1.9%]
CVA	**0.3%** (1)[0.0%,1.9%]	**0.3%** (1)[0.0%,1.9%]
In-Hospital	**0.0%** (0)[0.0%,1.2%]	**0.0%** (0)[0.0%,1.2%]
Out-of-Hospital	**0.3%** (1)[0.0%,1.9%]	**0.3%** (1)[0.0%,1.9%]
Vascular Complications	**3.4%** (10)[1.6%,6.1%]	**3.4%** (10)[1.6%,6.1%]
In-Hospital	**2.7%** (8)[1.2%,5.2%]	**2.7%** (8)[1.2%,5.2%]
Out-of-Hospital	**0.7%** (2)[0.1%,2.4%]	**0.7%** (2)[0.1%,2.4%]
Stent Delivery Failures	**0.0%** (0) [0.0%, 1.2%]	**0.0%** (0) [0.0%, 1.2%]

*Complications are based on patient totals. Seven patients had multiple adverse events: one patient had 3 vascular complications, four patients had 2 vascular complications), one patient had 1 non-Q MI and 1 bleeding. complication), and one patient had1 non-Q MI and 1 vascular complication.

[§]Adverse Event= Death, Q or Non-Q wave MI, Emergent CABG, Stent Thrombosis, CVA, Bleeding Complications, and Vascular Complications.
**All four deaths were non-cardiac.
Definitions for the terms used in Table 2 are found in the footnotes to Table 3.

5.2 Potential Adverse Events

Potential adverse events that may be associated with the use of a coronary stent in native coronary arteries (including those listed in Table 2) are listed below in order of severity:

- Death
- Emergency Coronary Artery Bypass Graft Surgery (CABG)
- Stroke/Cerebrovascular Accidents
- Cardiac tamponade
- Stent thrombosis or occlusion
- Total occlusion of coronary artery
- Acute myocardial infarction
- Restenosis of stented segments
- Perforation
- Arrhythmias, including ventricular fibrillation & ventricular tachycardia
- Dissection
- Emboli, distal (air, tissue or thrombotic emboli)
- Stent embolization
- Hemorrhage requiring transfusion
- Pseudoaneurysm, femoral
- Spasm
- Myocardial ischemia
- Hypotension/Hypertension
- Allergic reaction to drugs/contrast medium/stent material
- Peripheral ischemia
- Peripheral nerve injury
- Infection and pain at the insertion site
- Hematoma

CLINICAL TRIAL RESULTS

6.1 Driver DeNovo and Restenotic Registry

6.1.1 Purpose

The purpose of the Driver Registry was to evaluate the safety and efficacy of the Medtronic Driver stent for the treatment of single *denovo* or restenotic post-PTCA (non-stented) lesions in native coronary arteries.

6.1.2 Conclusions

The Driver Registry demonstrated the 180-day and 270-day safety and efficacy of the Driver stent for treatment of patients with *denovo* or restenotic lesions in native coronary arteries.

6.1.3 Design

A prospective, multi-center non-randomized study was conducted at 23 North American clinical sites enrolling 298 patients. Patients were 18 years of age or older with clinical evidence of ischemic heart disease or a positive functional study undergoing elective treatment for a single *denovo* or restenotic (post PTCA, non-stented) lesion in a native coronary artery. Eligible patients had visually estimated stenosis $\geq$ 50% and < 100% in a lesion $\leq$ 30 mm in length located in a major coronary artery or major side branch $\geq$ 3.0 mm and $\leq$ 4.0 mm in diameter.

The primary endpoint in the Driver DeNovo and Restenotic Registry was Major Adverse Cardiac Event (MACE) rate defined as the composite of death, Q wave and non-Q wave myocardial infarction, emergent bypass surgery, or target lesion revascularization (TLR) at 180 days. The primary endpoint was analyzed on an intent-to-treat basis, defined as patients who had the study device introduced into the guide catheter after determination that the subject and the target lesion met all inclusion criteria and none of the exclusion criteria.

The primary endpoint of MACE at 180 days was compared to an objective performance criterion (OPC) of 15% plus delta of 6%, based on a pooled MACE rate derived from the Bard XT Stent EXTRA RCT, Medtronic Micro Stent II SMART RCT, and Medtronic BeStent I (BEST) & BeStent II Registries. These studies had a range of 12.1% to 15.7% for MACE at 6 months compared to the Driver Registry 6 month MACE rate of 5.7% (17/298).

Secondary endpoints, (including acute success, target vessel failure (TVF) in hospital, at 14, 30, 180 and 270 days, clinically driven target lesion revascularization (TLR) at 180 and 270 days, binary angiographic restenosis ($\geq$ 50% in-stent diameter stenosis) at 180 days in the 101 patient subset, late loss at 180 days and ischemic, bleeding and vascular complications) were analyzed on a per-protocol evaluable basis, defined as patients who had successful procedures and were available for follow-up.

All patients received the hospital's standard anti-coagulation/anti-platelet regimen for coronary stent implantation. The ACT was kept at therapeutic levels for Percutaneous Coronary Intervention per the hospital standard.

6.1.4 Demographics

Of the 298 patients enrolled, baseline demographics and clinical characteristics showed a mean age of 62.6 years (range 26 to 88 years), 68.1% (203/298) were men, 27.6% (82/297) had a history of diabetes mellitus, 75.9% (221/291) had hyperlipidemia requiring treatment, 28.8% (83/288) were current smokers and 68.4% (201/294) had hypertension requiring treatment.

6.1.5 Methods

Patients in the Driver DeNovo and Restenotic Registry underwent balloon angioplasty (1:1 balloon to artery ratio) after which a stent of the appropriate length and diameter was selected and deployed. The Medtronic Driver Coronary Stent System could be repressurized up to 16 atm to further dilate the stent to assure complete apposition of the stent to the artery wall. If needed, further inflations were performed with a non-compliant balloon with a balloon-to-artery ratio of 1:1.
The anticoagulation regimen administered to 100% of the patients included 325 mg/day of aspirin for at least 14 days; plus either ticlopidine, 250 mg b.i.d. or clopidogrel 75 mg q.d for 14 days. Glycoprotein IIbIIIa platelet inhibitors were administered to 32.6% (97/298) of the patients during the index procedure.

Clinical or telephone follow-up was conducted in-hospital, and at 14, 30, 180 and 270 days post-procedure. A subset of 27.8% (83/298) patients underwent follow-up angiography at the 180 day clinical follow-up. Data monitoring was conducted by Medtronic personnel. Angiographic films were analyzed and revascularizations were adjudicated by an independent Angiographic Core Laboratory. An independent Clinical Events Committee adjudicated all other primary endpoints and Major Adverse Cardiac Events.

6.1.6 Results

The Driver Registry 180 day TVF rate was 5.0% (15/298) and the TVF rate at 270 days was 9.7% (29/298). Adverse events for both time points are listed in Table 2 and the Principal Safety and Effectiveness results are presented in Table 3.

The primary endpoint of MACE at 180 days was compared to an objective performance criterion (OPC), based on a pooled MACE rate derived from previous AVE/Medtronic/USCI-Bard trials, of 15% plus delta of 6%. Specifically, the OPC of 15% as derived by pooling the data from the Bard XT Stent EXTRA RCT, Medtronic Micro Stent II SMART RCT, and Medtronic BeStent I (BEST) & BeStent II Registries.

A test of the null hypothesis that the observed Driver MACE rate of 5.7% (17/298) is greater or equal to 21% (15% OPC + delta of 6%), provided an Exact Test (one-sided) p-value less than 0.0001, leading to a rejection of this null hypothesis and signifying equivalency with the OPC rate (i.e., Driver MACE rate significantly less than 21%). In a test for superiority, the Driver MACE rate was significantly less than the OPC of 15% itself (p=0.0082).

Table 3. Principal Effectiveness and Safety Results - Medtronic Driver Stent

Efficacy Measures	**Medtronic Driver Stent (N=298)**
Post-Procedure In-Stent Minimal Lumen Diameter (mm) Mean±SD (N) Range (min,max)	 2.90±0.42 (284) (1.52,4.12)[2.85 , 2.94]
Procedure In-Stent Percent Diameter Stenosis (% DS) Mean±SD (N) Range (min,max)	 3.05±10.50 (284) (-32.31,41.12)[1.83 , 4.27]
Device Success	100.0% (298)[98.8%, 100%]
Procedure Success	98.3% (293)[96.1%, 99.5%]
Binary Restenosis Rate	15.7% (13/83)
TLR-free at 180 Days*	96.2% [94.7%, 97.7%]
TLR-free at 270 Days*	91.2% [86.5%, 95.8%]
TVR-free at 180 Days*	95.5% [93.5%, 96.9%]
TVR-free at 270 Days*	90.0% [85.1%, 95.0%]
TVF-free at 180 Days*	92.8% [90.8%, 94.8%]
TVF-free at 270 Days*	88.3% [83.1%, 93.6%]
Safety Measures & Other Clinical Events	**Medtronic Driver Stent (N=298)**
In-Hospital MACE (Death, QMI,NQMI, TLR, Emergent CABG)	1.7% (5)[0.5%, 3.9%]
Out-of-Hospital MACE (Death, QMI, NQMI, TLR, Emergent CABG)	8.4% (25)[5.5%,12.1%]
MACE to 180 days (Death, QMI, NQMI, TLR, Emergent CABG)	5.7% (17)[3.4%, 9.0%]
MACE to 270 days (Death, QMI, NQMI, TLR, Emergent CABG)	10.1% (30) [6.9%,14.1%]
TLR rate at 180 days	3.4% (10) [1.6%,6.1%]
TLR rate at 270 days	7.0% (21) [4.4%, 10.6%}
TVR rate at 180 days	1.7% (5)[0.5%,3.9%]
TVR rate at 270 days	2.3% (7)[0.9%, 4.8%]
TVF rate at 180 days	6.7% (20) [4.1%, 10.2%]
TVF rate at 270 days	9.7% (29) [6.6%, 13.7%]
Bleeding Complications	2.3% (7)[0.9%,4.8%]
CVA	0.3% (1)[0.0%,1.9%]
Vascular Complications	3.4% (10)[1.6%,6.1%]
Stent Thrombosis	0.0% (0)[0.0%,1.2%]

MACE: Major Adverse Cardiac Event (includes death, MI, and emergent CABG or target lesion revascularization).

TLR free: No target lesion revascularization.
TVR free: No target vessel revascularization.
TVF free: No death, any MI or target vessel revascularization.
Binary restenosis: 50% or greater in-stent diameter stenosis at the follow-up angiogram.
Stent Thrombosis: Stent thrombosis was defined as total thrombotic stent occlusion documented by angiography.
In-hospital major clinical event: death, MI, emergent CABG, repeat target lesion revascularization, stent thrombosis, or stroke prior to discharge, as determined by the independent Clinical Events Committee.
Out-of-hospital major clinical event: death, MI, emergent CABG, repeat target lesion revascularization, stent thrombosis, or stroke after discharge, as determined by the independent Clinical Events Committee.
Vascular complications; may include pseudoaneurysm, arteriovenous fistula, peripheral ischemia/nerve injury or vascular event requiring transfusion or surgical repair.
Bleeding complications: transfusions due to blood loss resulting from the percutaneous revascularization procedure.
CVA: sudden onset of vertigo, numbness, dysphasia, weakenss, visual field defects, dysarthria or other focal neurological deficits due to vascular lesions of the brain, such as hemorrhage, embolism, thrombosis, or rupturing aneurysm, that persists greater than 24 hours.
Device success: Attainment of <30% in-stent residual stenosis using the randomized treatment strategy only.
Procedure success: <50% stenosis in-stent (or in-lesion if no in-stent measurement available) and freedom from in-hospital major adverse cardiac events (death, MI, emergent CABG, or repeat target lesion revascularization).
*Survival estimates by Kaplan-Meier method; Standard Error estimates by Greenwood formula

6.2 PREDICT Trial

Based on acceptable performance in *de novo* lesions and the similarities in design and manufacture of the DRIVER Coronary Stent System to the Medtronic S670™ and Medtronic S7 Coronary Stent Systems, the following study, which evaluated direct stenting using the Medtronic S670 Coronary Stent, also supports the suitability of direct stenting for delivery of the Medtronic Driver Coronary Stent System.

The PREDICT Trial was a prospective, multi-center study using the S670™ OTW Coronary System randomized to either direct stenting or standard predilatation deployment technique. The study was conducted at 37 North American clinical sites and included a total of four hundred (400) randomized patients and sixteen (16) roll-in patients with *denovo* native coronary artery lesions. A clinical events committee adjudicated all major clinical events and clinically driven TLR.

6.2.1 Primary Endpoint

The primary endpoint in the PREDICT Trial was Major Adverse Cardiac Event (MACE) rate defined as the composite of death, Q wave and non-Q wave myocardial infarction, emergent coronary artery bypass surgery, or target lesion revascularization (TLR) at 14 days.

6.2.2 Patients Studied

The 399 patients (65.7% male) treated ranged in age from 29 to 87 years with an average of 64 ± 11.6 (mean ± SD) years. All patients presented with angina or a positive functional study and were undergoing elective single *denovo* lesion treatment in a native coronary artery. Eligible patients had visually estimated stenosis ≤ 15 mm in length in a major coronary artery or major side branch ≥ 3.0 mm and ≤ 4.0 mm in diameter. One patient withdrew consent after randomization but before investigational treatment was attempted.

6.2.3 Methods

Patients in the PREDICT Trial were randomized to either direct stenting (without predilatation) or standard pre-dilatation by balloon angioplasty (1:1 balloon to artery ratio) after which a stent system(s) of the appropriate length and diameter was selected and deployed. The Medtronic AVE S670™ OTW stent delivery system could be repressurized up to 16 atm to further dilate the stent to assure complete apposition of the stent to the artery wall. If needed, further inflations were performed with a non-compliant balloon with a balloon-to-artery ratio of 1:1. Clinical follow-up was conducted up to 6 months.

The anticoagulation regimen administered to 97% (389/399) of the patients at discharge was 325 mg aspirin and either 500 mg ticlopidine or 300 mg clopidogrel. The follow-up regimen administered to 83% (333/399) of the patients was 325 mg/day ASA for at least six month; ticlopidine 250 mg twice a day or clopidogrel 75 mg daily.

Clinical follow-up intervals for all treated PREDICT patients were 14 days, 30 days and 6 months. All patients underwent angiographic follow-up at 6 months for the PREDICT Trial. The study randomization was successful, as both treatment groups were demographically equivalent. All treated randomized patients were included in the intent-to-treat efficacy analysis. The principal effectiveness and safety for the PREDICT Trial for direct stenting versus predilatation are shown in table 4.

6.2.4 Conclusions

The success rate for the direct stenting arm was 92.0% (185/201). The sixteen patients who crossed over to the pre-dilatation arm were treated successfully. There were no statistically significant differences between the two arms with respect to Major Adverse Cardiac Events.

Table 4. Principal Effectiveness and Safety Results PREDICT Trial
S670 PREDICT Patients Treated (N = 399)

Efficacy Measures	Direct Stenting (N=198 Patients, N=201 Lesions)	Pre-Dilatation (N=201 Patients, N=203 Lesions)	All Randomized* (N=399 Patients, N=404 Lesions)	Relative Risk [95% C.I.]	Difference [95% C.I.]	P-value
Primary Device Success	92.0% (185 / 201)	96.6% (196 / 203)	94.3% (381 / 404)	0.95 [0.91,1.00]	-4.5% [-9.0%,0.0%]	0.056
Secondary Device Success	99.5% (200 / 201)	99.0% (200 / 202)	99.3% (400 / 403)	1.00 [0.99,1.02]	0.5% [-1.2%,2.2%]	1.000
Procedure Success	93.9% (186 / 198)	92.5% (185 / 200)	93.2% (371 / 398)	1.02 [0.96,1.07]	1.4% [-3.5%,6.4%]	0.691
Post-Procedure In-Lesion Minimal Lumen Diameter (MLD, in mm)						
Mean±SD (N)	2.54±0.55 (199)	2.56±0.50 (199)	2.55±0.52 (398)	N/A	-0.02 [-0.12,0.09]	0.739
Range (min,max)	(1.34,4.29)	(1.37,4.01)	(1.34,4.29)			
Post-Procedure In-Lesion Percent Diameter Stenosis (% DS)						
Mean±SD (N)	18.9%±9.8% (199)	18.3%±11.1% (199)	18.6%±10.5% (398)	N/A	0.6% [-1.5%,2.6%]	0.585
Range (min,max)	(1.5%,55.6%)	(-27.7%,54.2%)	(-27.7%,55.6%)			
Post-Procedure In-Stent Minimal Lumen Diameter (MLD, in mm)						
Mean±SD (N)	2.92±0.43 (199)	2.98±0.42 (199)	2.95±0.43 (398)	N/A	-0.06 [-0.14,0.03]	0.185
Range (min,max)	(1.84,4.30)	(2.10,4.34)	(1.84,4.34)			
Post-Procedure In-Stent Percent Diameter Stenosis (% DS)						
Mean±SD (N)	5.9%±9.4% (199)	4.5%±9.3% (199)	5.2%±9.4% (398)	N/A	1.4% [-0.5%,3.2%]	0.150
Range (min,max)	(-24.1%,35.8%)	(-34.7%,27.0%)	(-34.7%,35.8%)			
In-Lesion Acute Gain (mm)						
Mean±SD (N)	1.60±0.60 (199)	1.66±0.58 (199)	1.63±0.59 (398)	N/A	-0.06 [-0.18,0.06]	0.302
Range (min,max)	(0.11,3.74)	(0.06,2.97)	(0.06,3.74)			
In-Stent Acute Gain (mm)						
Mean±SD (N)	1.98±0.53 (199)	2.08±0.52 (199)	2.03±0.53 (398)	N/A	-0.10 [-0.20,0.00]	0.056
Range (min,max)	(0.77,3.74)	(0.34,3.59)	(0.34,3.74)			
In-Lesion Binary Restenosis Rate	26.5% (43 / 162)	25.8% (42 / 163)	26.2% (85 / 325)	N/A	0.8% [-8.8%,10.3%]	0.900
In-Stent Binary Restenosis Rate	20.4% (33 / 162)	20.9% (34 / 163)	20.6% (67 / 325)	N/A	-0.5% [-9.3%,8.3%]	1.000
TLR-free to 180 days†	80.2%	82.6%	81.5%	0.97 [0.78,1.21]	-2.4% [-20.0%,15.3%]	0.846
TVR-free to 180 days†	79.3%	79.3%	79.3%	1.00 [0.80,1.26]	0.0% [-18.1%,18.1%]	0.643
TVF-free to 180 days†	72.9%	72.5%	72.7%	1.01 [0.77,1.32]	0.4% [-19.4%,20.1%]	0.677
MACE-free to 180 days†	73.8%	74.5%	74.1%	0.99 [0.76,1.29]	-0.7% [-20.2%,18.9%]	0.770
Safety Measures and Other Clinical Events						
In-Hospital MACE	5.6% (11 / 198)	7.0% (14 / 201)	6.3% (25 / 399)	0.80 [0.37,1.71]	-1.4% [-6.2%,3.3%]	0.681
Out-of-Hospital MACE to 14 days	0.5% (1 / 198)	0.5% (1 / 201)	0.5% (2 / 399)	1.02 [0.06,16.17]	0.0% [-1.4%,1.4%]	1.000
MACE to 14 days	6.1% (12 / 198)	7.5% (15 / 201)	6.8% (27 / 399)	0.81 [0.39,1.69]	-1.4% [-6.3%,3.5%]	0.691
Out-of-Hospital MACE to 180 days	13.1% (26 / 198)	13.9% (28 / 201)	13.5% (54 / 399)	0.94 [0.57,1.55]	-0.8% [-7.5%,5.9%]	0.884
MACE to 180 days	18.7% (37 / 198)	19.4% (39 / 201)	19.0% (76 / 399)	0.96 [0.64,1.44]	-0.7% [-8.4%,7.0%]	0.899
Abrupt Closure to 180 days	0.0% (0 / 198)	1.5% (3 / 201)	0.8% (3 / 399)	0.00 [—,—]	-1.5% [-3.2%,0.2%]	0.248
Subacute Closure to 180 days	0.0% (0 / 198)	0.5% (1 / 201)	0.3% (1 / 399)	0.00 [—,—]	-0.5% [-1.5%,0.5%]	1.000
Stent Thrombosis to 180 days	0.5% (1 / 198)	0.5% (1 / 201)	0.5% (2 / 399)	1.02 [0.06,16.17]	0.0% [-1.4%,1.4%]	1.000
CVA to 180 days	0.0% (0 / 198)	0.0% (0 / 201)	0.0% (0 / 399)	— [—,—]	0.0% [—,—]	N/A
Bleeding Complications to 180 days	1.5% (3 / 198)	1.0% (2 / 201)	1.3% (5 / 399)	1.52 [0.26,8.91]	0.5% [-1.7%,2.7%]	0.684
Vascular Complications to 180 days	7.1% (14 / 198)	4.0% (8 / 201)	5.5% (22 / 399)	1.78 [0.77,4.09]	3.1% [-1.4%,7.6%]	0.194

†. One patient withdrew consent after randomization but before the investigational treatment was attempted and was deregistered.

Primary Device Success = The attainment of a <50% residual in-stent (or in-lesion in the absence of in-stent) stenosis (by QCA) of the target site using the assigned treatment strategy alone, (i.e. only the Medtronic AVE S670™ stent without pre-dilatation if so randomized) during the index catheterization. If QCA was not available, the visual estimate of diameter stenosis was used. Post-dilatation with a high pressure or larger balloon was considered part of the treatment strategy for both arms, but tracked as to frequency. The need for pre-dilatation in patients randomized to direct stenting arm was considered a primary device failure and use of other brands of stents besides the Medtronic AVE S670™.

Secondary Device Success = The attainment of a <50% residual in-stent (or in-lesion in the absence of in-stent) stenosis (by QCA) of the target site using any strategy (including stent withdrawal, pre-dilatation or pre-treatment with another device, and a repeat attempt at stent implantation). If QCA was not available, the visual estimate of diameter stenosis was used. Post-dilatation with a high pressure or larger balloon was considered part of the treatment strategy for both arms, but tracked as to frequency.

Procedure Success = The attainment of a <50% in-stent (or in-lesion in the absence of in-stent) residual stenosis (by QCA) at the target site using any strategy and freedom from Major Adverse Cardiac Events prior to hospital discharge. If QCA was not available, the visual estimate of diameter stenosis was used.

In-Hospital MACE = Death, Q wave or non-Q wave MI, emergent CABG, or target lesion revascularization prior to discharge as determined by the independent Clinical Events Committee.

Out-of-Hospital MACE = Death, Q wave or non-Q wave MI, emergent CABG, or target lesion revascularization from hospital discharge through the 180-day contact, as determined by the independent Clinical Events Committee.

TLR-free = No target lesion revascularization.

TVR-free = No target vessel revascularization.

TVF-free = No death, MI, or target vessel revascularization.

Footnotes are continued on the following page.

MACE-free = No death, MI, emergent CABG, or target lesion revascularization.
Abrupt Closure = Occurrence of new severely reduced flow (TIMI grade 0 or 1) within the target vessel that persisted and required rescue by a non-assigned treatment strategy, or resulted in MI or death.
Subacute Closure = Abrupt closure that occurred after the index procedure was completed and within 30 days of the index procedure.
Stent Thrombosis = Angiographic thrombus or subacute closure within the stented vessel, or any death not attributed to a non-cardiac cause in the absence of documented angiographic stent patency within the first 30 days.
CVA = Acute neurological deficits recorded by the clinical sites that persisted >24 hours.
Bleeding Complications = Defined as transfusions of blood products due to blood loss from the percutaneous revascularization procedure.
Vascular Complications = Defined as hematoma >4 cm, false aneurysm, AV fistula, retroperitoneal bleed, peripheral ischemia/nerve injury, procedure related transfusion or vascular surgical repair.
Acute Gain = Acute gain was defined as the immediate dimensional change in minimal luminal diameter (in mm) that occurred as a result of the procedure, measured by quantitative coronary angiography based on data interpolated from two orthogonal views at baseline and after the final post dilatation.

7. PATIENT SELECTION AND TREATMENT

7.1 Individualization of Treatment

The risks and benefits described above should be carefully considered for each patient before use of the Medtronic Driver Multi-Exchange Coronary Stent System. Patient selection factors to be assessed should include a judgment regarding risk of prolonged anticoagulation. Stenting should be generally avoided in those patients at heightened risk of bleeding (e.g., those patients with recently active gastritis or peptic ulcer disease) (see Contraindications).

Co-morbidities that increase the risk of poor initial results or the risks of emergency referral for bypass surgery (diabetes mellitus, renal failure, and severe obesity) should be reviewed.

Thrombosis following stent implantation is affected by several baseline angiographic and procedural factors. These include vessel diameter less than 3.0 mm, intra-procedural thrombosis, poor distal flow, and/or dissection following stent implantation. In patients that have undergone coronary stenting, the persistence of a thrombus or dissection is considered a marker for subsequent thrombotic occlusion. These patients should be monitored very carefully during the first month after stent implantation.

7.2 Use in Special Populations

The safety and effectiveness of the Medtronic Driver Multi-Exchange Coronary Stent System have not been established in:

- Patients with **unresolved vessel thrombus at the lesion site**.
- Patients with coronary artery **reference vessel diameters < 3.0 mm**.
- Patients with **lesions located in the unprotected left main coronary artery**, **ostial lesions**, or **lesions located at a bifurcation**.
- Patients with diffuse disease or **poor outflow distal** to the identified lesions.
- Patients with recent **acute myocardial infarction** where there is evidence of thrombus or poor flow.
- Patients with **more than two overlapping stents** due to risk of thrombosis or poor flow.
- Patients beyond the **nine month follow-up** period

The safety and effectiveness of using mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters), or laser angioplasty catheters, to treat in-stent stenosis have not been established.

6. CLINICIAN USE INFORMATION

8.1 Inspection Prior to Use

Carefully inspect the sterile package before opening. It is not recommended that the product be used after the "Use By" date. If the integrity of the sterile package has been compromised prior to the product "Use By" date (e.g., damage of the package) contact your local Medtronic, Inc. Representative for return information. If the sterile package appears intact, carefully remove the system from the package and inspect for bends, kinks and other damage. Verify that the stent is located between the radiopaque markers. Do not use if any defects are noted.

8.2 Materials Required

Quantity	Material
	Appropriate guiding catheter. (see Table 1- Device Specifications)
1	20 cc syringe.
	Heparinized normal saline.
1	Maximum 0.014 inch guidewire without sinusoidal waves/curves on the distal portion of the guidewire.
1	Rotating hemostatic valve.
	Contrast medium diluted 1:1 with heparinized normal saline.
1	Inflation device.
1	Torque device.
Optional	Three-way stopcock.

8.3 Preparation

8.3.1 Guidewire Lumen Flush

Step	Action
1	Remove protective sheath covering from the stent/balloon. Care should be taken not to disrupt the stent.
2	Flush Stent Delivery System guidewire lumen with heparinized normal saline through the distal end of the catheter by attaching the blunt end of a syringe to the distal end of the catheter and flushing the guidewire lumen until fluid exits from the guideway and/or the Z component.
3	Verify that the stent is positioned between the proximal and distal balloon markers.

8.3.2 Delivery System Preparation

Step	Action
1	Fill a 20 cc syringe with 5 cc of contrast/heparinized normal saline mixture (1:1).
2	Attach to delivery system and apply negative pressure for 20-30 seconds.
3	Slowly release pressure to allow negative pressure to draw mixture into balloon lumen.
4	Detach syringe and leave a meniscus of mixture on the hub of the balloon lumen.
5	Prepare inflation device in standard manner and purge to remove all air from syringe and tubing.
6	Attach inflation device to catheter directly ensuring no bubbles remain at connection.
7	Leave on ambient pressure (neutral position). **Note: Do not pull negative pressure on inflation device after balloon preparation** and prior to delivering the stent.
8	Moisten the stent with heparinized normal saline by submerging the stent into a sterile bowl containing the solution. **Note: Do not use gauze sponges to wipe down the stent as fibers may disrupt the stent.**
9	Visually inspect the stent to ensure the stent is placed within the area of the proximal and distal balloon markers.

8.4 Delivery Procedure

Step	Action
1	Prepare vascular access site according to standard PTCA practice.
2	Pre-dilate the lesion/vessel with appropriate diameter balloon having a ratio of 1:1 with the diameter of the vessel. This step may be eliminated if direct stenting is performed.
3	Maintain neutral pressure on inflation device. Open rotating hemostatic valve to allow for easy passage of the stent. **Note:** If resistance is encountered, **do not force passage**. Resistance may indicate a problem and may result in damage to the stent if it is forced. Remove the system and examine.
4	Ensure guiding catheter stability before advancing the Stent Delivery System into the coronary artery. Carefully advance the distal tip of the Stent Delivery System over the proximal end of the guidewire. Ensure that the guidewire exits the Stent Delivery System catheter through the Z component. Advance the stent delivery system over the guidewire through a large-bore hemostatic valve adapter using conventional angioplasty techniques.
5	Carefully advance the stent delivery system through the guiding catheter until the tip of the Z component enters the hemostatic valve adapter. Once the Z component is positioned properly, it will not advance any further into the hemostatic valve adapter. **Note:** Once the distal section of the delivery system is in the guide catheter, always ensure the Z component is adjacent to the hemostatic valve adapter (during shaft advancement, retraction, etc.).
6	Gradually tighten the hemostatic valve adapter to control back flow. **Excessive hemostatic valve tightening may affect balloon inflation/deflation time as well as movement of the guidewire and proximal shaft.**
7	**Note:** If initial resistance to movement is encountered while advancing the catheter, this may indicate that the hemostatic valve adapter has been overtightened.
8	**Note:** If the physician encounters resistance to the Stent Delivery System prior to exiting the guiding catheter, **do not force passage**. Resistance may indicate a problem and may result in damage to the stent if it is forced. Maintain guidewire placement across the lesion and remove the Stent Delivery System as a single unit. (see Stent/System Removal – Precautions)

9	Advance delivery system over the guidewire to the target lesion under direct fluoroscopic visualization. Utilize the proximal and distal radiopaque markers on the balloon as a reference point. If the position of the stent is not optimal, it should be carefully repositioned or removed. (see Stent/System Removal - Precautions) Expansion of the stent should not be undertaken if the stent is not properly positioned in the target lesion segment of the vessel.
10	With the Z component adjacent to the hemostatic valve adapter, ensure there is no air in the system and the valve is securely closed around the proximal shaft prior to the injection of contrast medium.
11	Optimal stent placement requires the distal end of the stent to be placed approximately 1 mm beyond the distal end of the lesion.

8.5 Deployment Procedure

Step	Action
1	Deploy stent by inflating balloon to nominal pressure to expand the stent. **Note:** Refer to product labeling and Table 5 for the proper stent inflation pressure. The Medtronic Driver MX Coronary Stent System may be reinflated beyond nominal, without repositioning, up to rated burst, to assure complete apposition of the stent to the artery wall. **Do not exceed Rated Burst Pressure (16 ATM). Do not expand the stent beyond 5.0 mm.**
2	Maintain inflation pressure for 15-30 seconds for full expansion of the stent.
3	**Note:** Under-expansion of the stent may result in stent movement. Care must be taken to properly size the stent to ensure the stent is in full contact with the arterial wall upon deflation of the balloon.

8.6 Guidewire Interchange (If performed)

Step	Action
1	Withdraw the guidewire while maintaining balloon catheter position.
2	Taking care not to damage the guidewire tip, insert the new guidewire into the proximal end of the Z component while ensuring that the Z component remains adjacent to the hemostatic valve adapter. **Note**: The "Wire Introducer Tool", packaged with the hemostatic valve, may also be used to aid the loading of the new guidewire into the proximal end of the Z component.
3	Advance the guidewire to reach and cross the lesion.

8.7 Removal Procedure

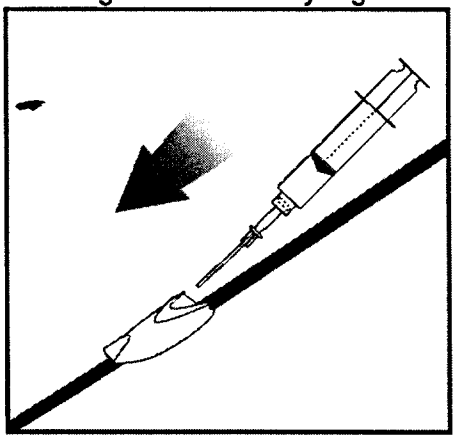
Step	Action
1	Deflate the balloon by pulling negative pressure on the inflation device. Allow adequate time, at least 15 seconds, for full balloon deflation. Longer stents may require more time for deflation.
2	Open the hemostatic valve to allow removal of the delivery system.
3	Maintain position of guiding catheter and guidewire to prevent it from being drawn into the vessel. Very slowly, withdraw the balloon from the stent maintaining negative suction, allowing movement of the myocardium to gently dislodge the balloon from the stent.
4	After removal of the delivery system, tighten the hemostatic valve.
5	Repeat angiography and visually assess the vessel and the stent for proper expansion.
6	A second balloon inflation may be required to insure optimal stent expansion. In such instances, the Medtronic Driver balloon may be reinflated up to rated burst pressure or a non-compliant, higher-pressure balloon of adequate size (the same size as the Stent Delivery System balloon or larger) and length may be used to accomplish this. **Note:** In smaller or diffusely diseased vessels, the use

	of high balloon inflation pressures may over-expand the vessel distal to the stent and could result in vessel dissection. **Do not exceed Rated Burst Pressure (16 ATM). Do not expand the Medtronic Driver stent beyond 5.0 mm.**
7	The final internal stent diameter should be equal to or slightly larger than the proximal and distal reference vessel diameters.
8	Repeat angiography to evaluate and determine procedure status or termination. **Note:** Should the need arise for placement of a second stent to adequately cover the lesion length, placement of the stent most distal in the artery should be done prior to placement of the proximal stent, if possible.
9	**Note:** Observation of the patient and angiographic evaluation of the stent site should be performed periodically within the first 30 minutes after stent placement. If stent placement is associated with the onset of thrombus or suspected thrombus in the region of the stented segment, intracoronary infusions of a thrombolytic agent is recommended.

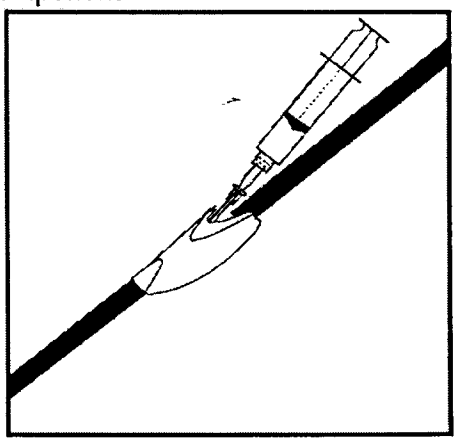
8.8 Reintroduction of Driver MX Coronary Stent System (If performed)

Step	Action
	If the delivery system is removed from the patient and reintroduced later in the procedure, flush the guidewire lumen prior to reintroduction as follows:
1	Retract the Z component to its most proximal position on the stent delivery catheter.
2	Fill a 20 cc syringe with 20 cc of heparinized saline solution.
3	Attach the syringe to the flushing cannula provided.
4	Insert the flushing cannula and attached syringe into the proximal end of the Z component as shown in Figure 2 below.
5	While holding the delivery system over a saline basin, flush the lumen while advancing the Z component to its most extended distal position. **Note**: Flushing medium may seep from the guideway during flushing.
6	Reintroduce the delivery system into the patient following step 9.4.

Figure 2. Flushing Cannula and Syringe on Z Component



Flushing cannula and syringe prior to insertion into Z component.



Flushing cannula and syringe in place on Z component.

8.9 Stent / Delivery System Removal Precautions

If removal of a stent system is required prior to deployment, ensure that the guide catheter is coaxially positioned relative to the stent system and cautiously withdraw the stent system into the guide catheter.

Should **unusual resistance** be felt **at any time**, when withdrawing the stent towards the guide catheter,, the Stent Delivery System and the guiding catheter **should be removed as a single unit**. This must be done under direct visualization with fluoroscopy.

When removing the Stent Delivery System and guiding catheter as a single unit:

- **Do not retract the Stent Delivery System into the guiding catheter.** Maintain guidewire placement across the lesion and carefully pull back the Stent Delivery System until the proximal balloon marker of the Stent Delivery System is aligned with the distal tip of the guiding catheter.

- The guiding catheter and the Stent Delivery System should be carefully removed from the coronary artery as a single unit.

- The system should be pulled back into the descending aorta toward the arterial sheath. As the distal end of the guiding catheter enters into the arterial sheath, the catheter will straighten, allowing safe withdrawal of the Stent Delivery System into the guiding catheter and the subsequent removal of the Stent Delivery System and the guiding catheter from the arterial sheath.

Failure to follow these steps and/or applying excessive force to the Stent Delivery System can potentially result in loss or damage to the stent and/or Stent Delivery System components such as the balloon.

Table 5. Medtronic Driver Stent Inner Diameter (mm) vs. Inflation Pressure (ATM)

	MEDTRONIC DRIVER STENT INNER DIAMETER (MM) Average Stent Inner Diameter (mm) Following Deployment:												
Stent Diameter	6 ATM	7 ATM	8 ATM	9* ATM	10 ATM	11 ATM	12 ATM	13 ATM	14 ATM	15 ATM	16** ATM	17 ATM	18 ATM
3.0mm	2.8	2.9	2.9	3.0	3.0	3.0	3.1	3.1	3.1	3.2	3.2	3.3	3.3
3.5mm	3.3	3.3	3.4	3.5	3.5	3.5	3.6	3.6	3.7	3.7	3.8	3.8	3.9
4.0mm	3.8	3.8	3.9	4.0	4.0	4.1	4.1	4.2	4.2	4.2	4.3	4.3	4.4

*Nominal Deployment Pressure (9 ATM)
Rated Burst Pressure. **DO NOT EXCEED.

NoteThe nominal *in vitro* device specification does not take into account lesion resistance. Stent sizing should be confirmed angiographically.
Note: Do not expand the stent beyond 5.0 mm.
Note: Balloon pressures should be monitored during inflation. Do not exceed Rated Burst Pressure as specified on product label as this may result in a ruptured balloon with possible intimal damage and dissection.

9. Patient Information (United States only)

In addition to the Instructions for Use, the Medtronic Driver Multi-Exchange Coronary Stent System is packaged with additional specific information which includes:

- A Patient Guide which includes information on Medtronic, Inc., the implant procedure and Medtronic, Inc. coronary stents.
- A Coronary Stent Implant Card that includes both patient information, stent implant information and MRI guidelines. All patients will be instructed to keep this card in their possession at all times for procedure/stent identification. (Note: The Coronary Stent Implant Card is located in the back of the Patient Guide.)

Protected under one or more of the following U.S. Patents: 4,988,356; 5,292,331; 5,674,278; 5,800,509; 5,836,965; 5,879,382; 5,891,190; 6,159,229; 6,190,358; 6,309,402; 6,344,053; 6,605,057; and other U.S. and foreign patents pending.

DISCLAIMER OF WARRANTY

NOTE: ALTHOUGH THE MEDTRONIC CORONARY STENT SYSTEM, HEREAFTER REFERRED TO AS "PRODUCT," HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, MEDTRONIC, INC., MEDTRONIC VASCULAR, INC. AND THEIR AFFILIATES (COLLECTIVELY, "MEDTRONIC") HAVE NO CONTROL OVER CONDITIONS UNDER WHICH THIS PRODUCT IS USED. MEDTRONIC, THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESSED AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. MEDTRONIC SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND MEDTRONIC TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

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